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(54) **BIFURCATION STENT AND METHOD OF POSITIONING IN A BODY LUMEN**

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(58) **Field of Classification Search**
None
See application file for complete search history.

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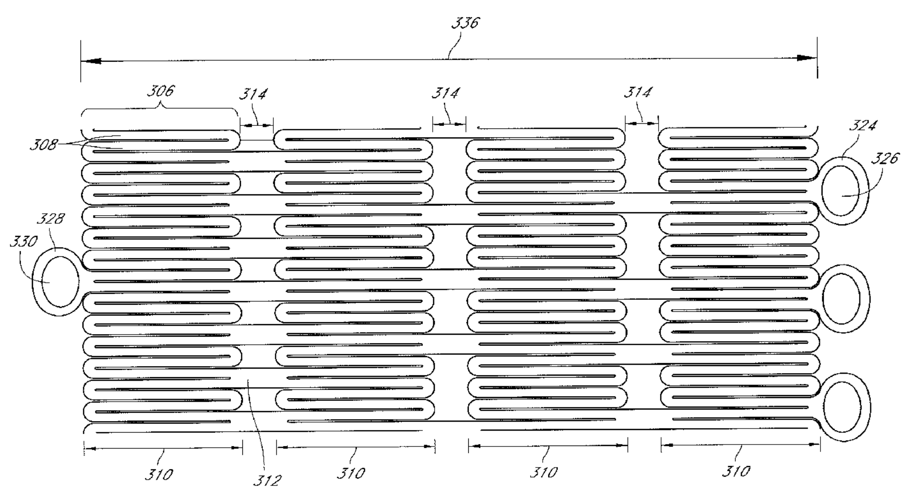
(57) **ABSTRACT**

Disclosed is a stent that is useful for treating a vascular bifurcation, the stent having a plurality of segments extending coaxially end to end along a longitudinal axis of the stent from a first end to a second end of the stent, each segment having a plurality of struts extending in a zig-zag pattern around the circumference of the stent, wherein the stent is expandable from reduced diameter to an expanded diameter, the second end of the stent having a larger diameter than the first end when expanded; and an eyelet integrally formed with the segment positioned adjacent the second end, and configured to receive a radiopaque marker therein. The stent provides an improvement over prior stents for treating a vascular bifurcation by allowing the stent to be deployed in the widened transitional zone of a bifurcation such that the second end of the stent is accurately positioned at the carina.

19 Claims, 28 Drawing Sheets



Related U.S. Application Data

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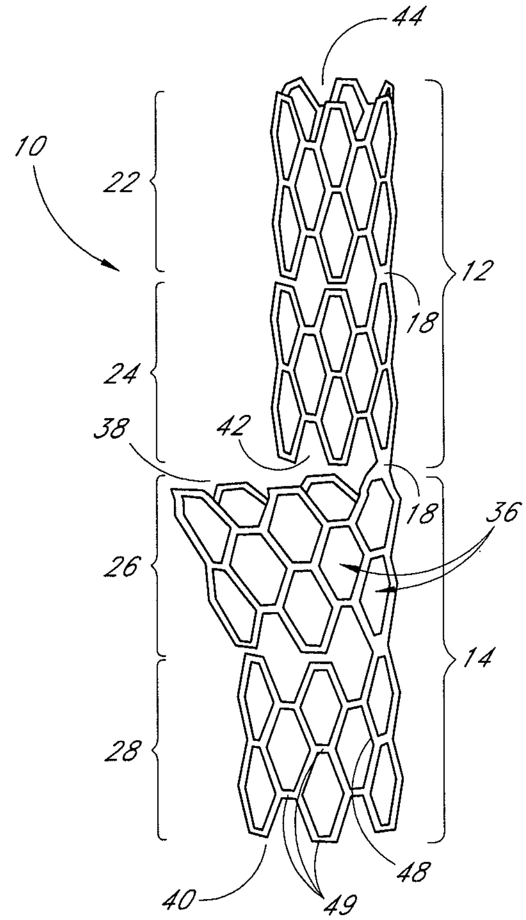

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FIG. 1

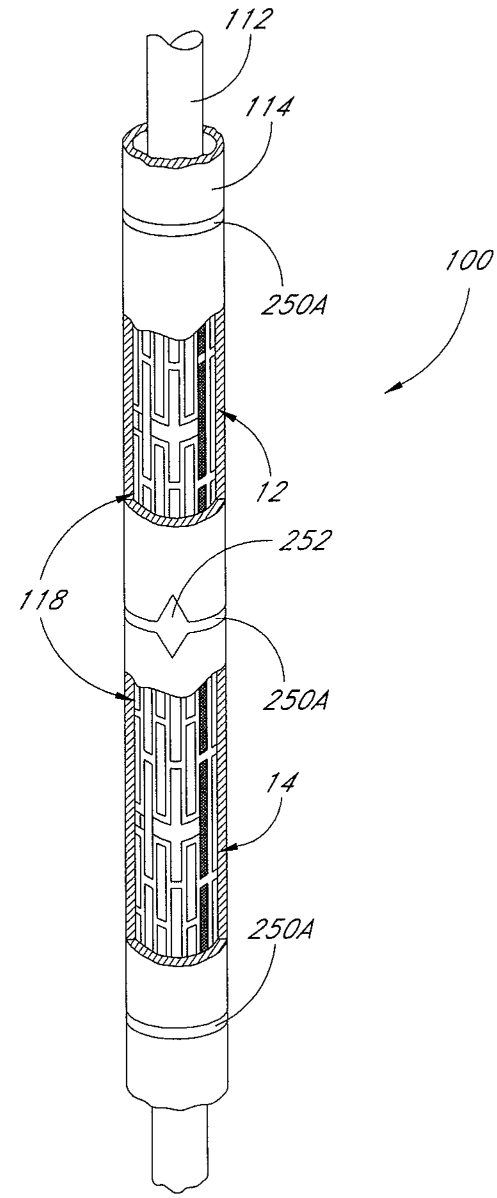

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FIG. 2

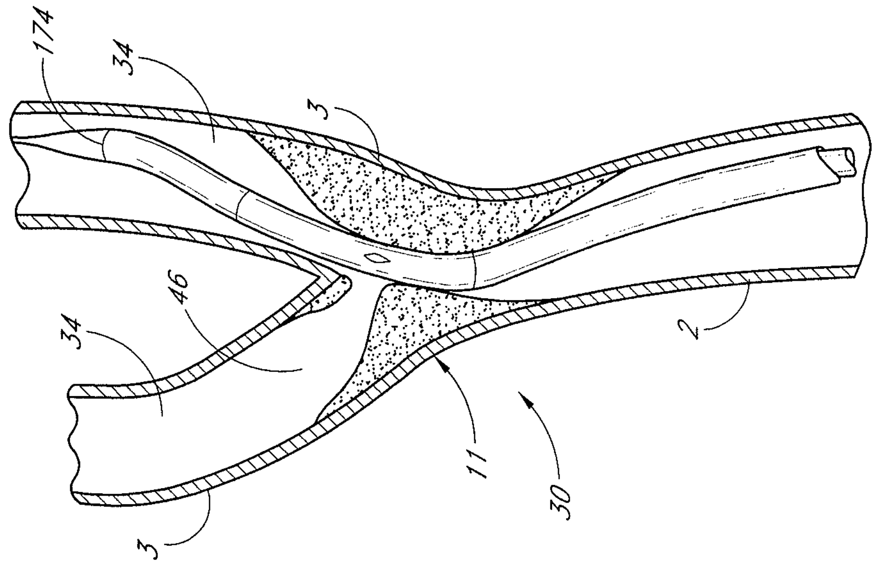

FIG. 4

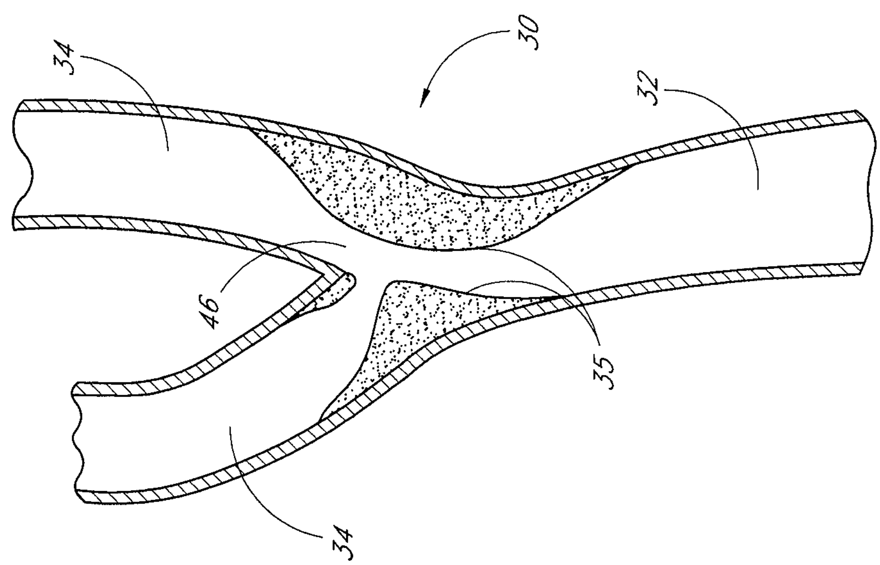

FIG. 3

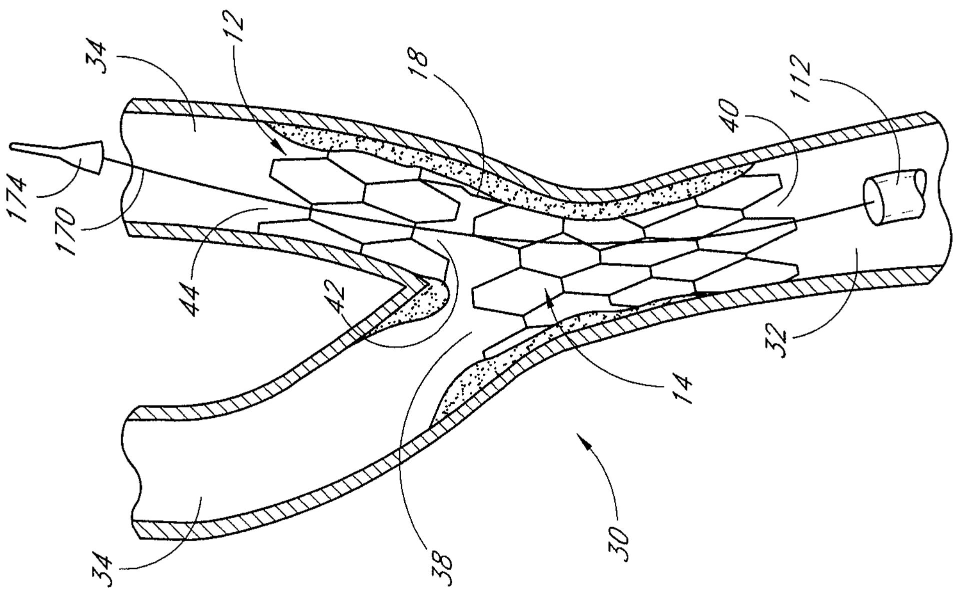

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FIG. 6

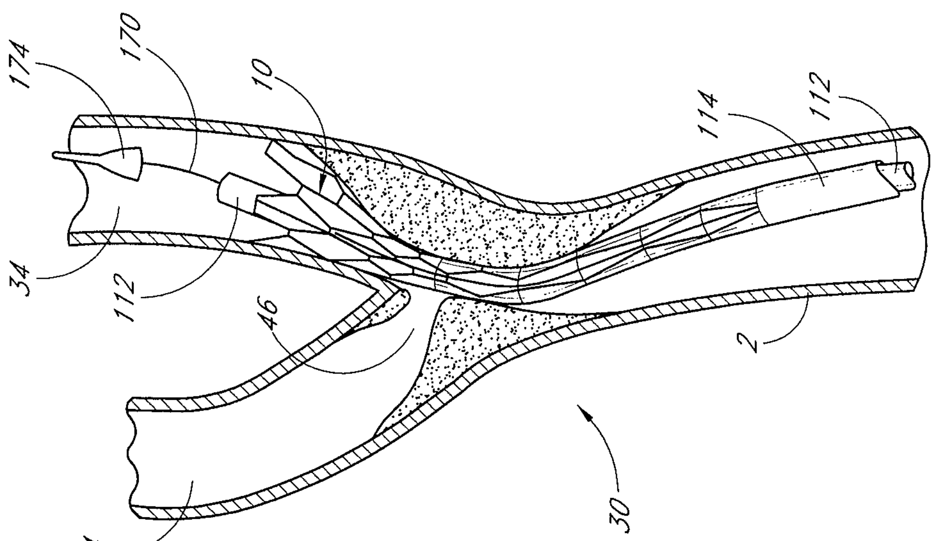

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FIG. 5

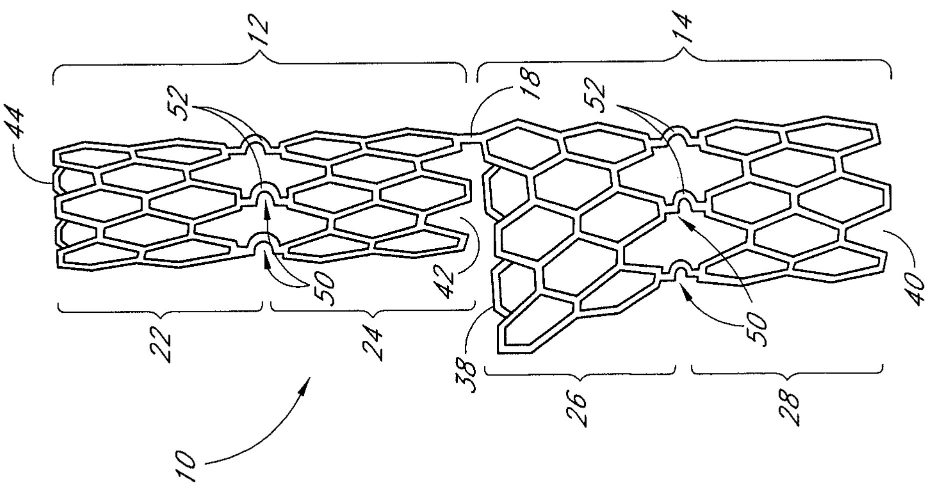
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FIG. 8

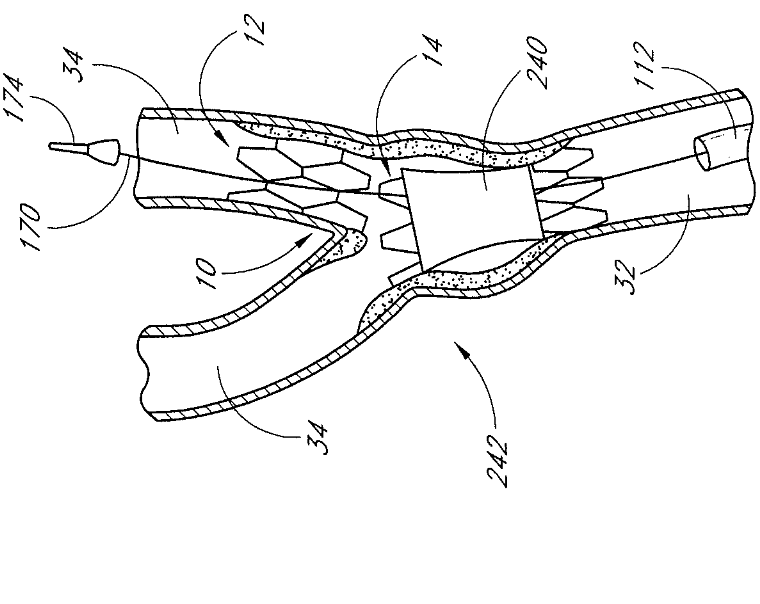
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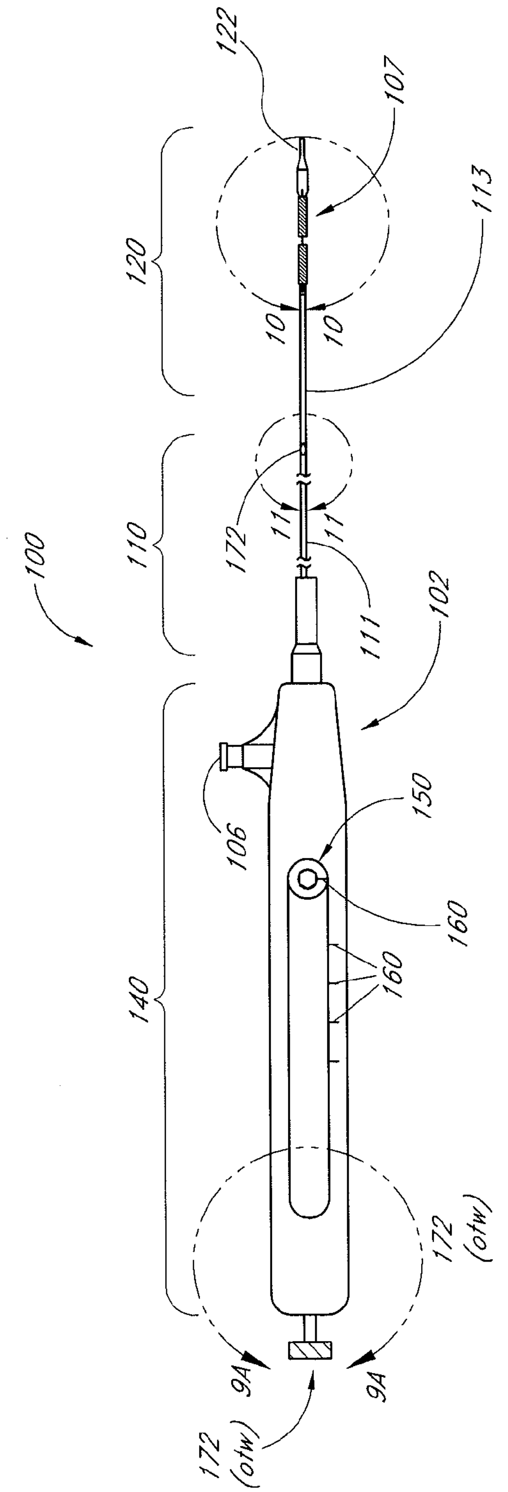
FIG. 7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172 (otw)
9A
9A
172 (otw)

FIG. 9

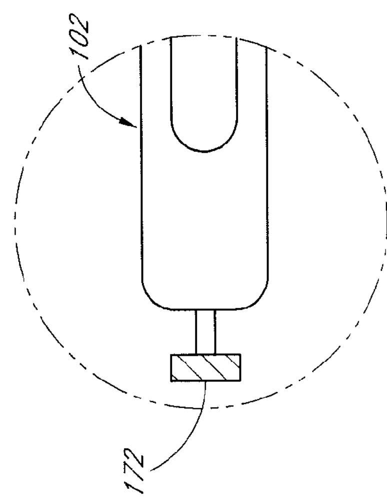
102
172

FIG. 9A

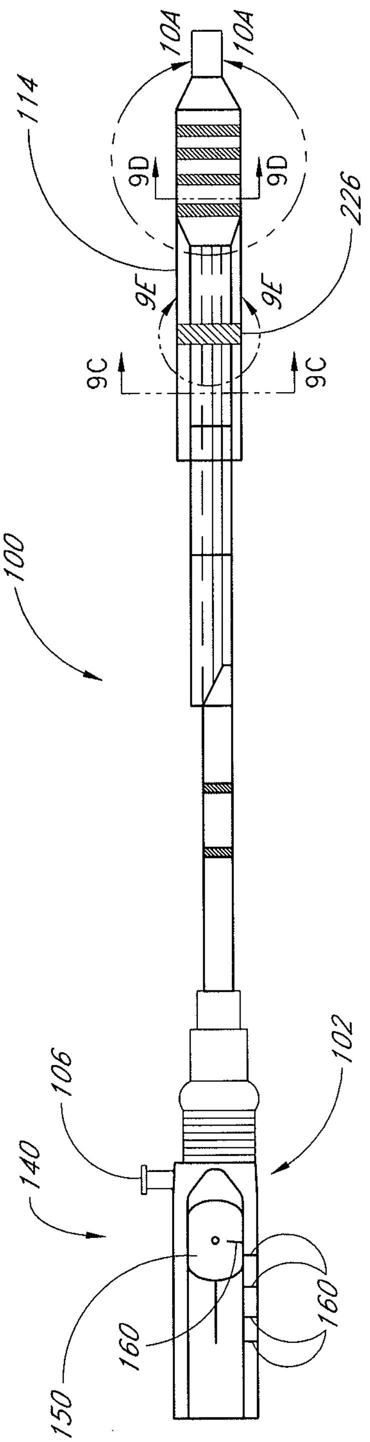

FIG. 9B

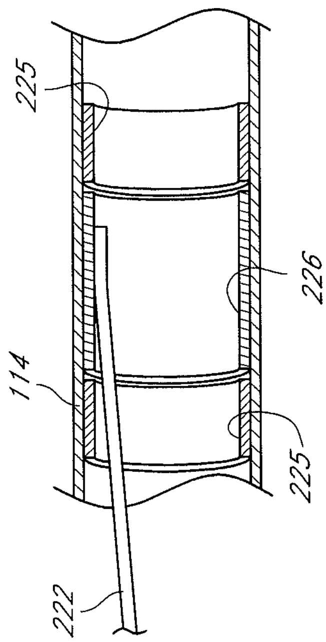

FIG. 9E

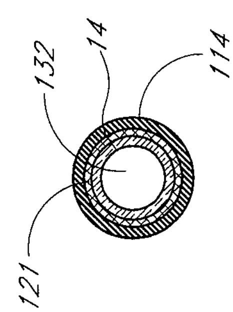

FIG. 9D

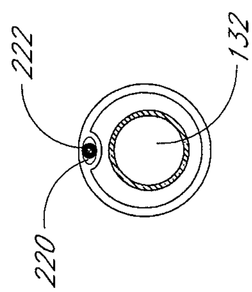

FIG. 9C

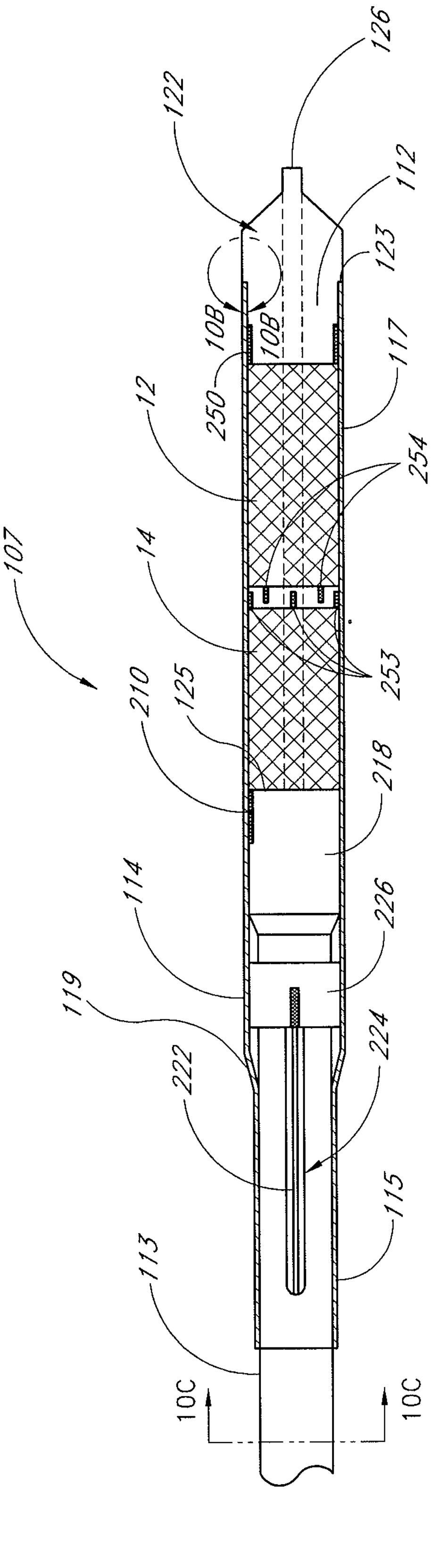

FIG. 10

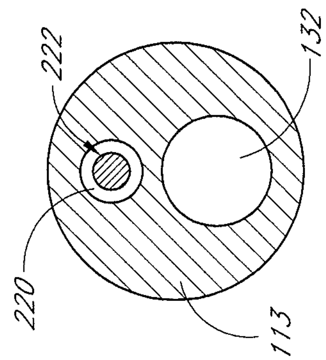

FIG. 10C

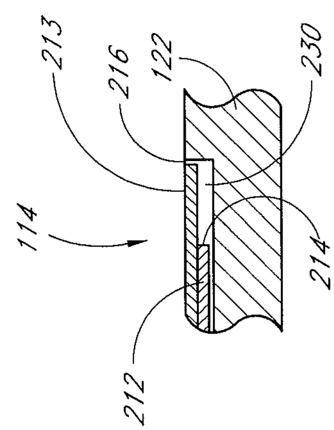

FIG. 10B

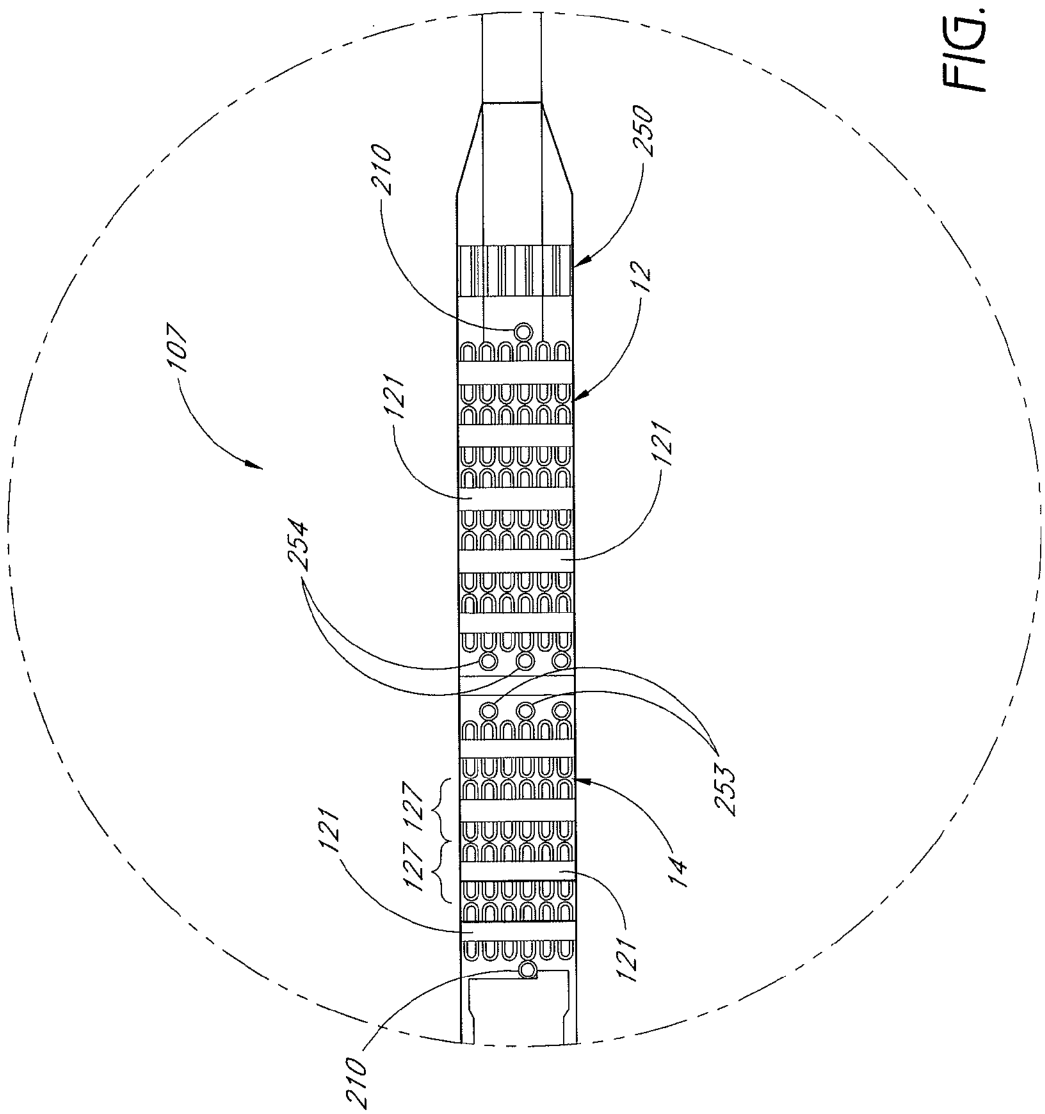

FIG. 10A

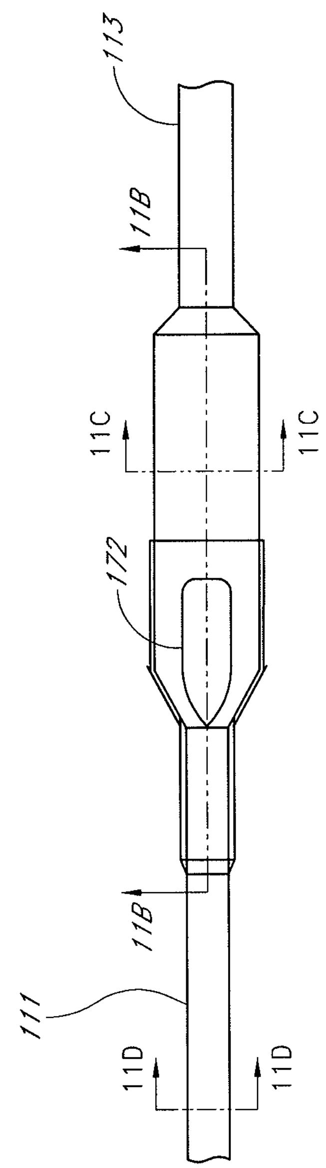

FIG. 11A

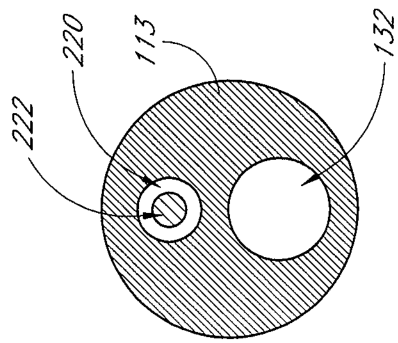

FIG. 11C

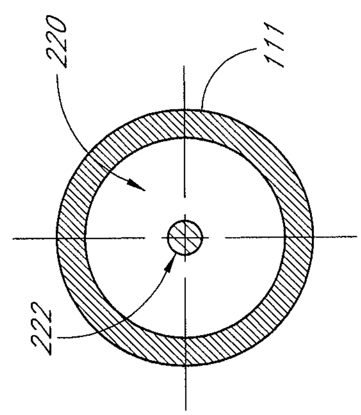

FIG. 11D

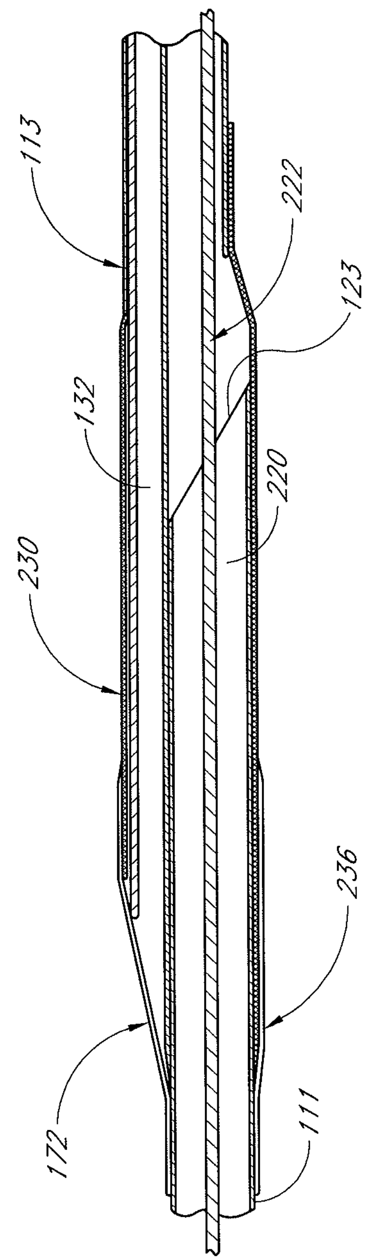

FIG. 11B

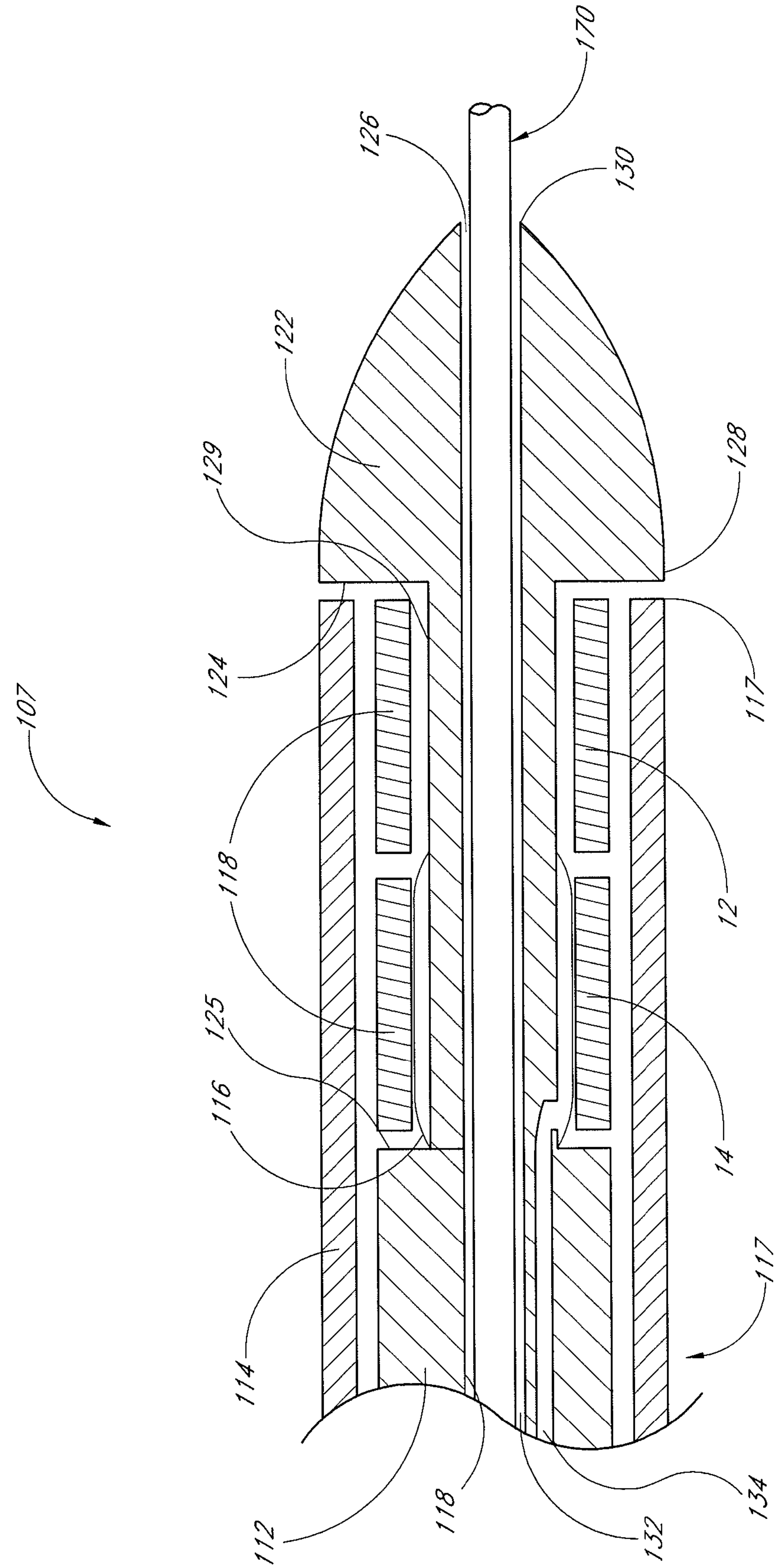
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FIG. 12

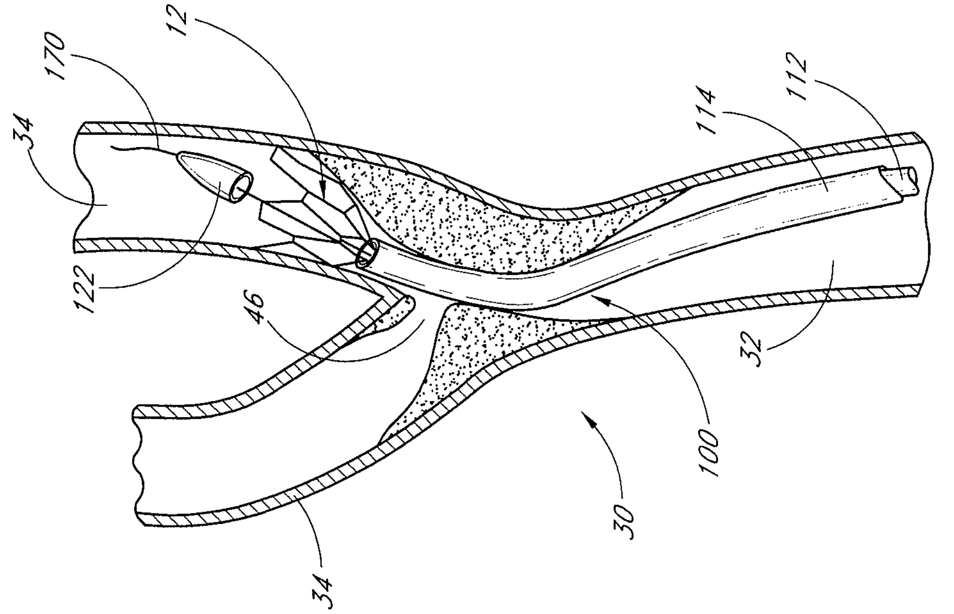
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FIG. 14

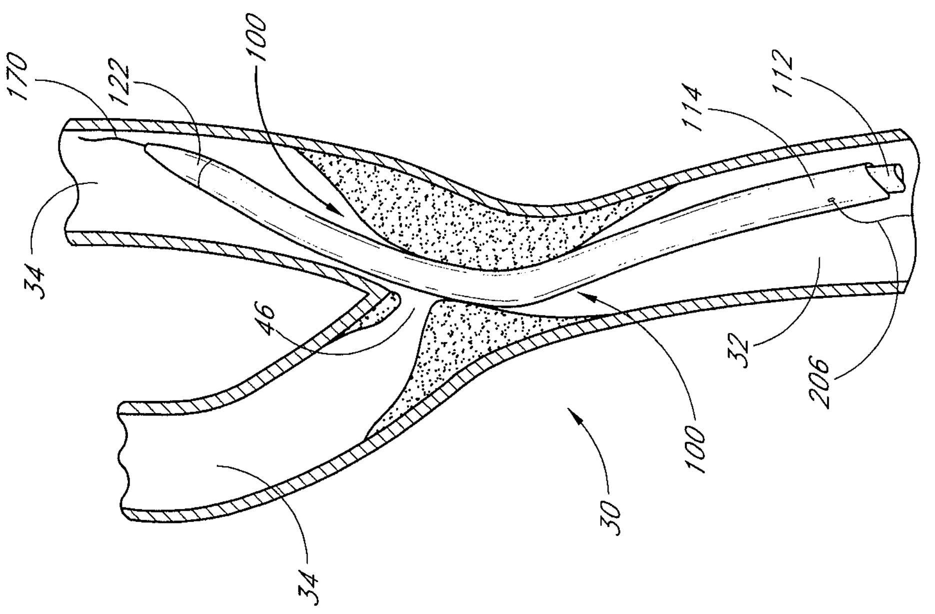
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FIG. 13

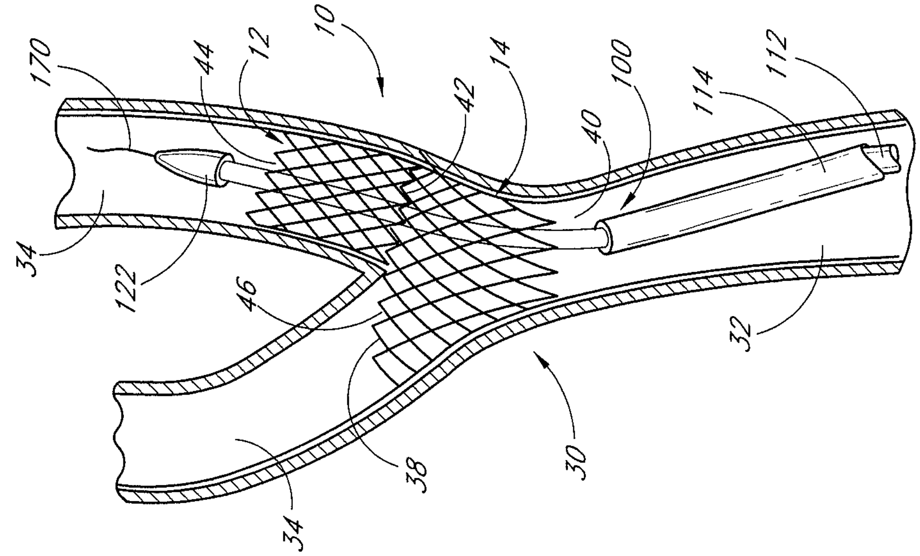

FIG. 17

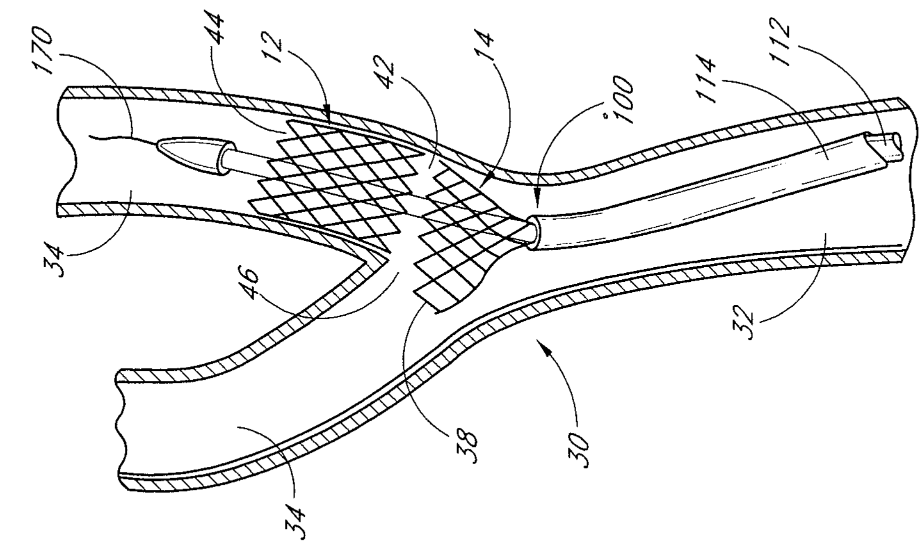

FIG. 16

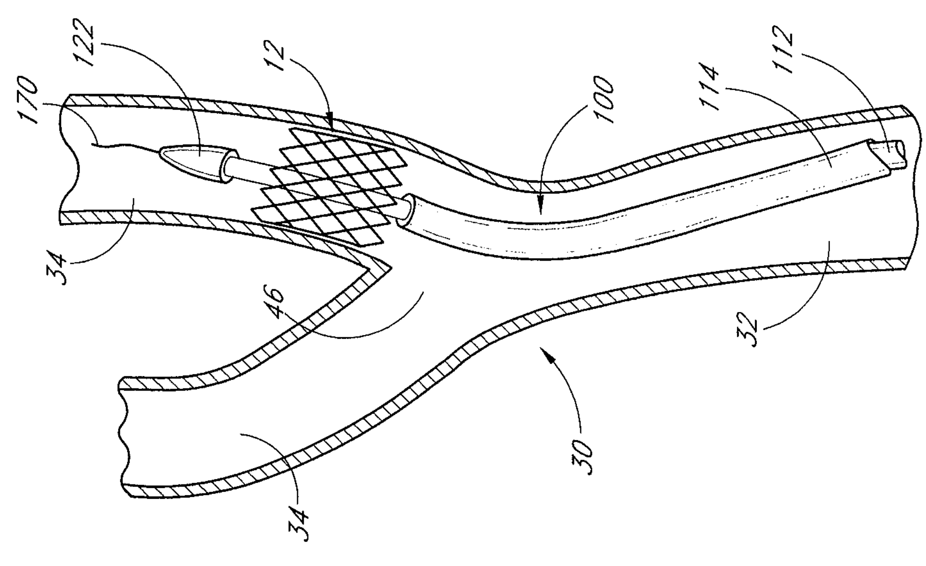

FIG. 15

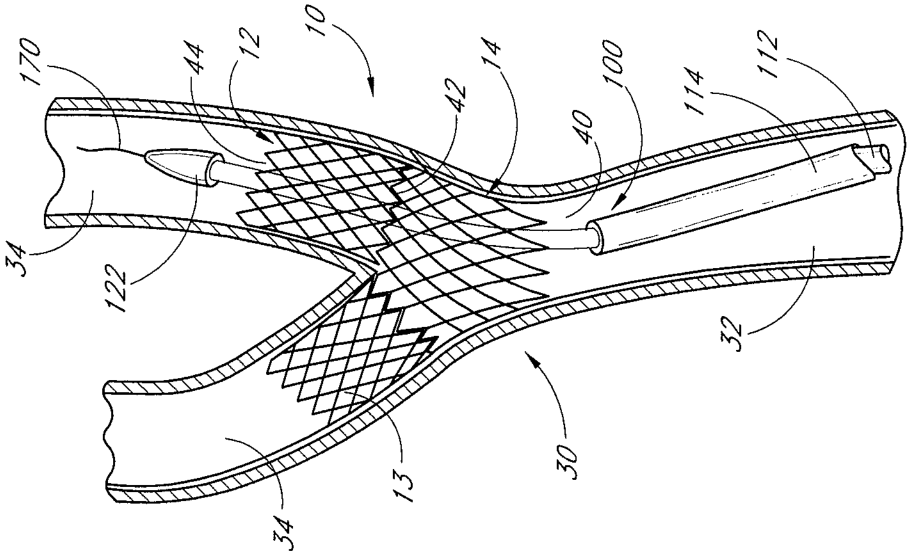

FIG. 18

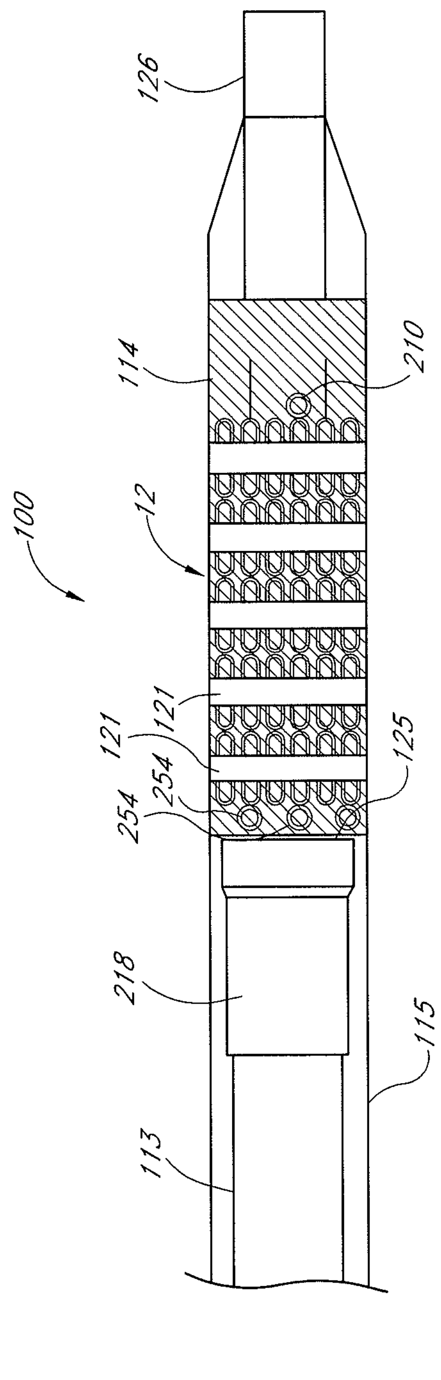
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FIG. 19

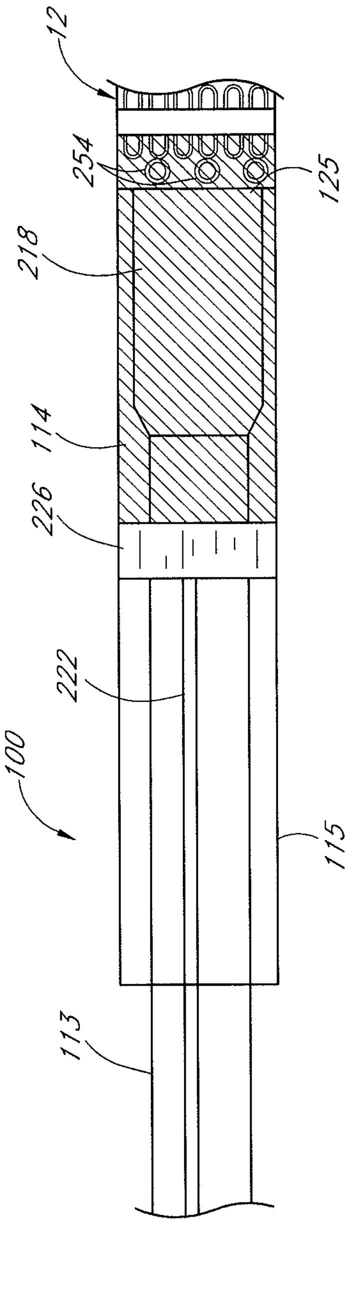
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FIG. 20

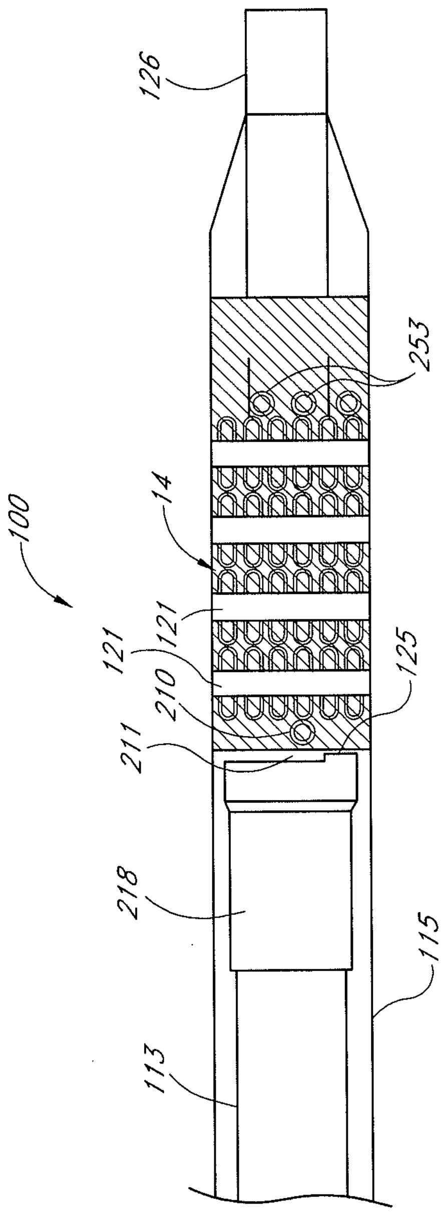
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FIG. 21

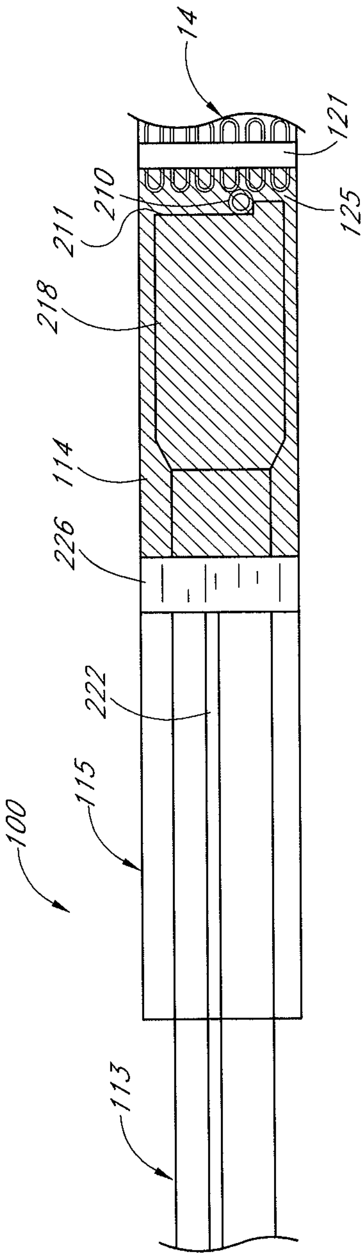
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FIG. 22

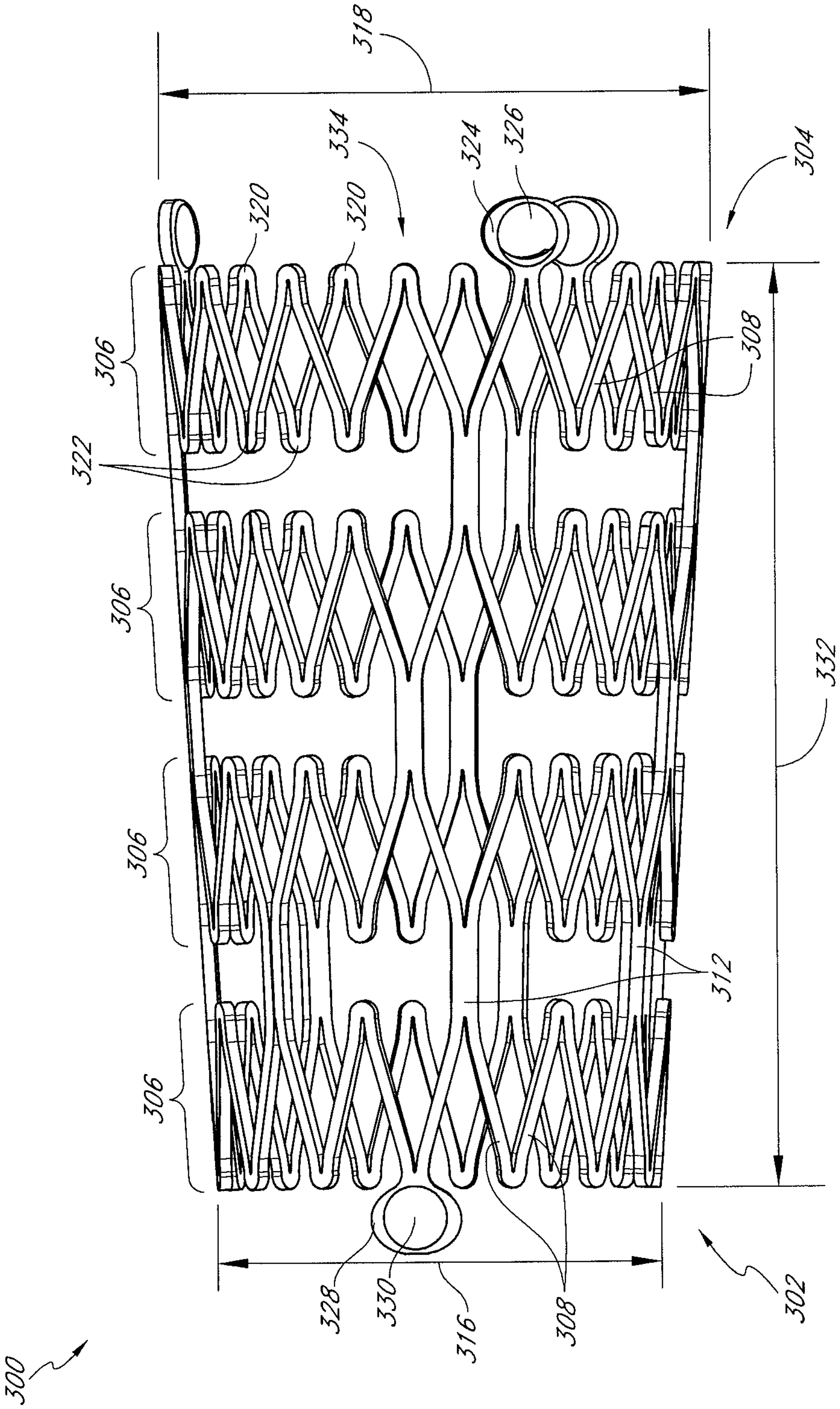
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FIG. 23A

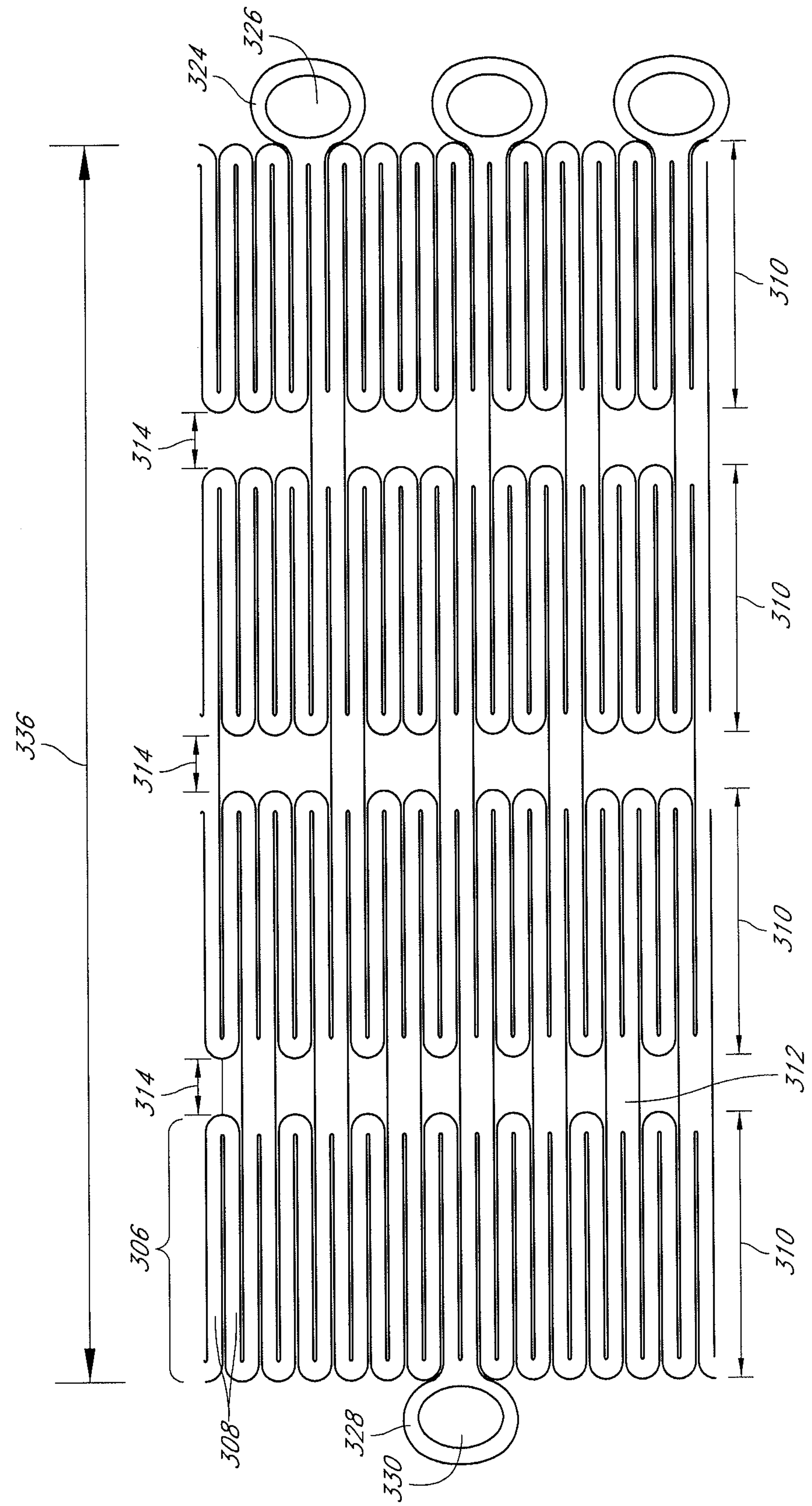

FIG. 23B

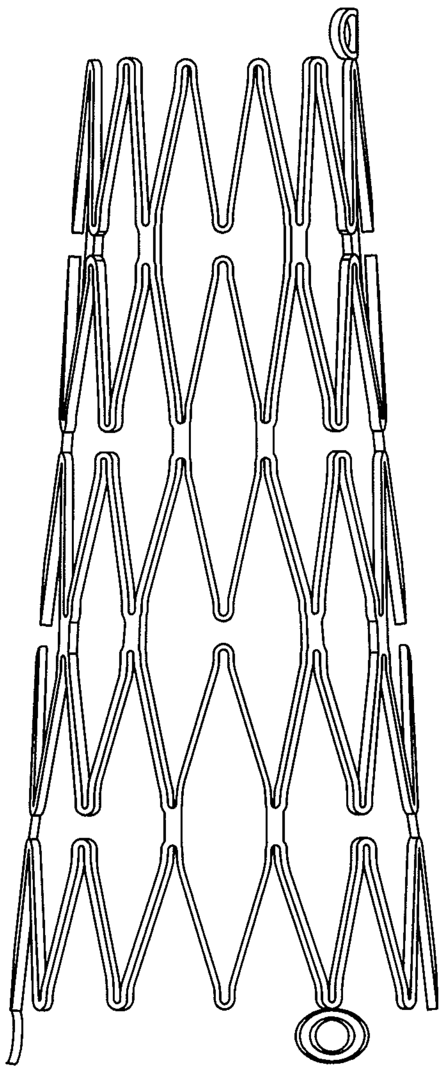

FIG. 23C

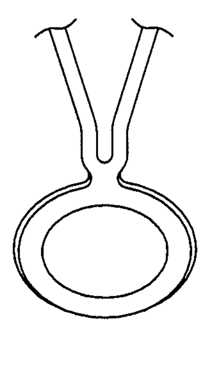

FIG. 23D

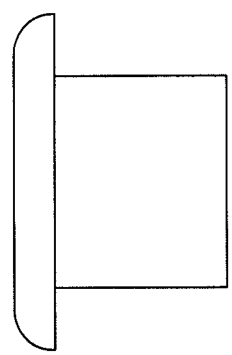

FIG. 23E

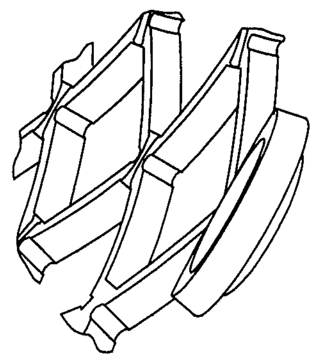

FIG. 23F

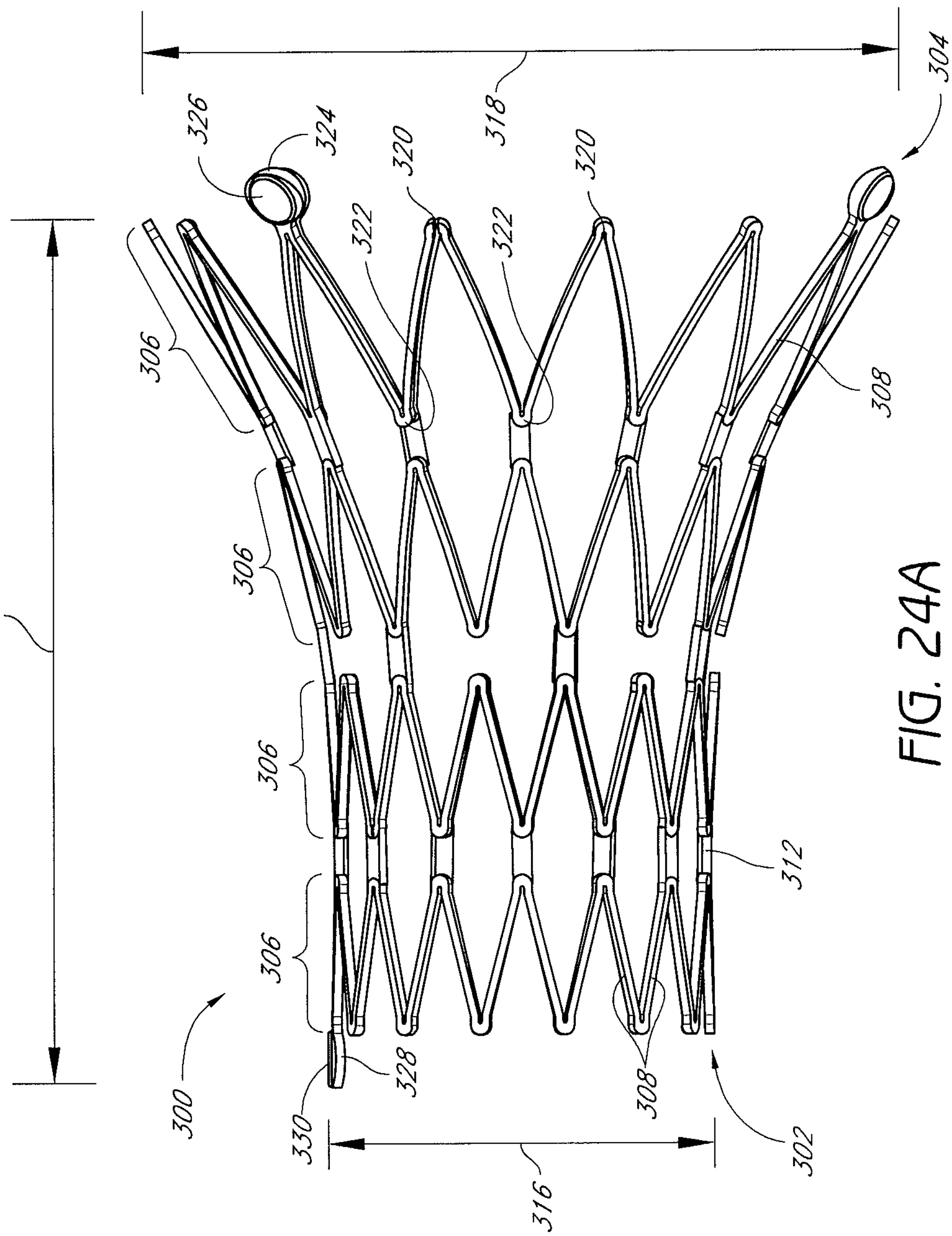
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FIG. 24A

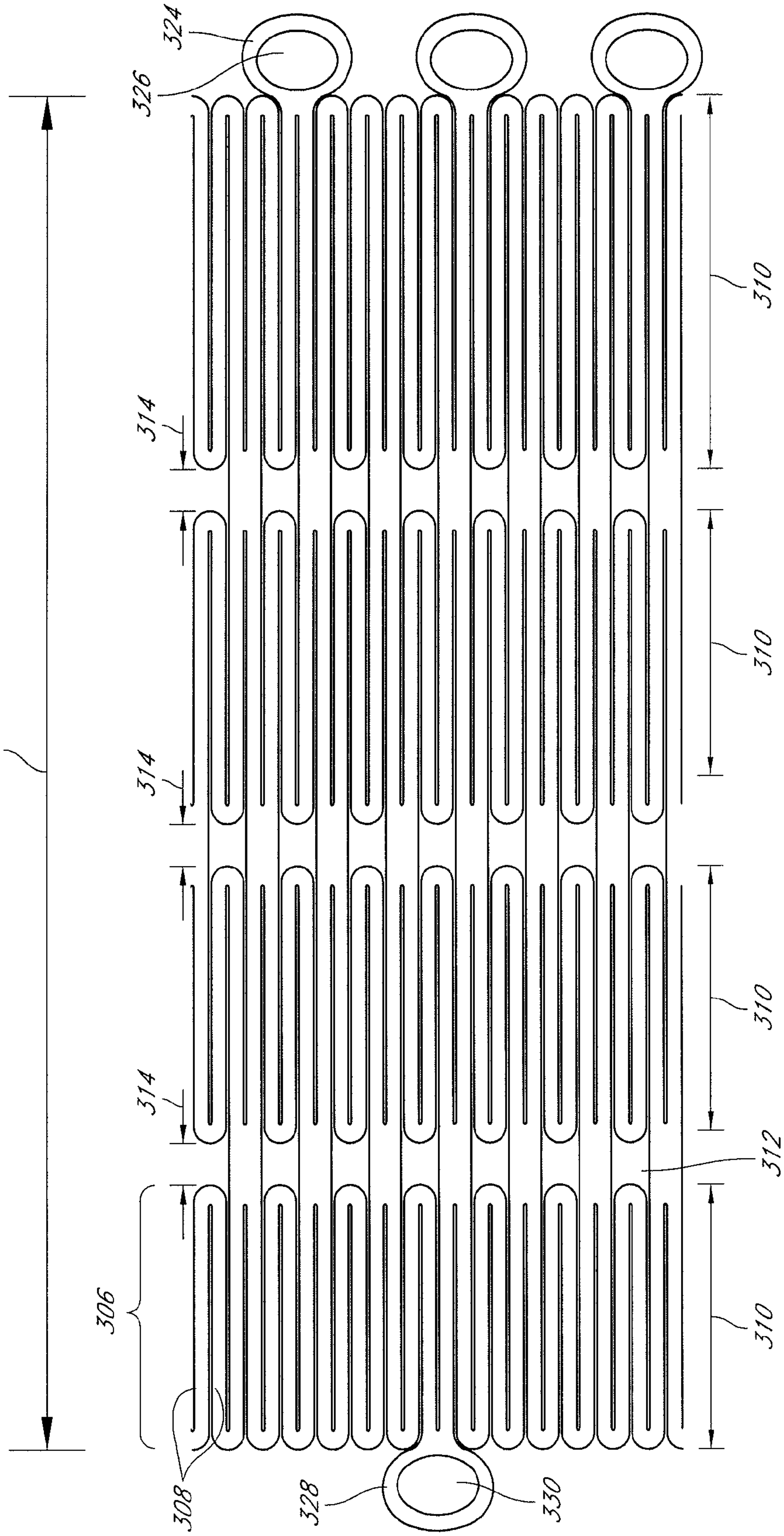

FIG. 24B

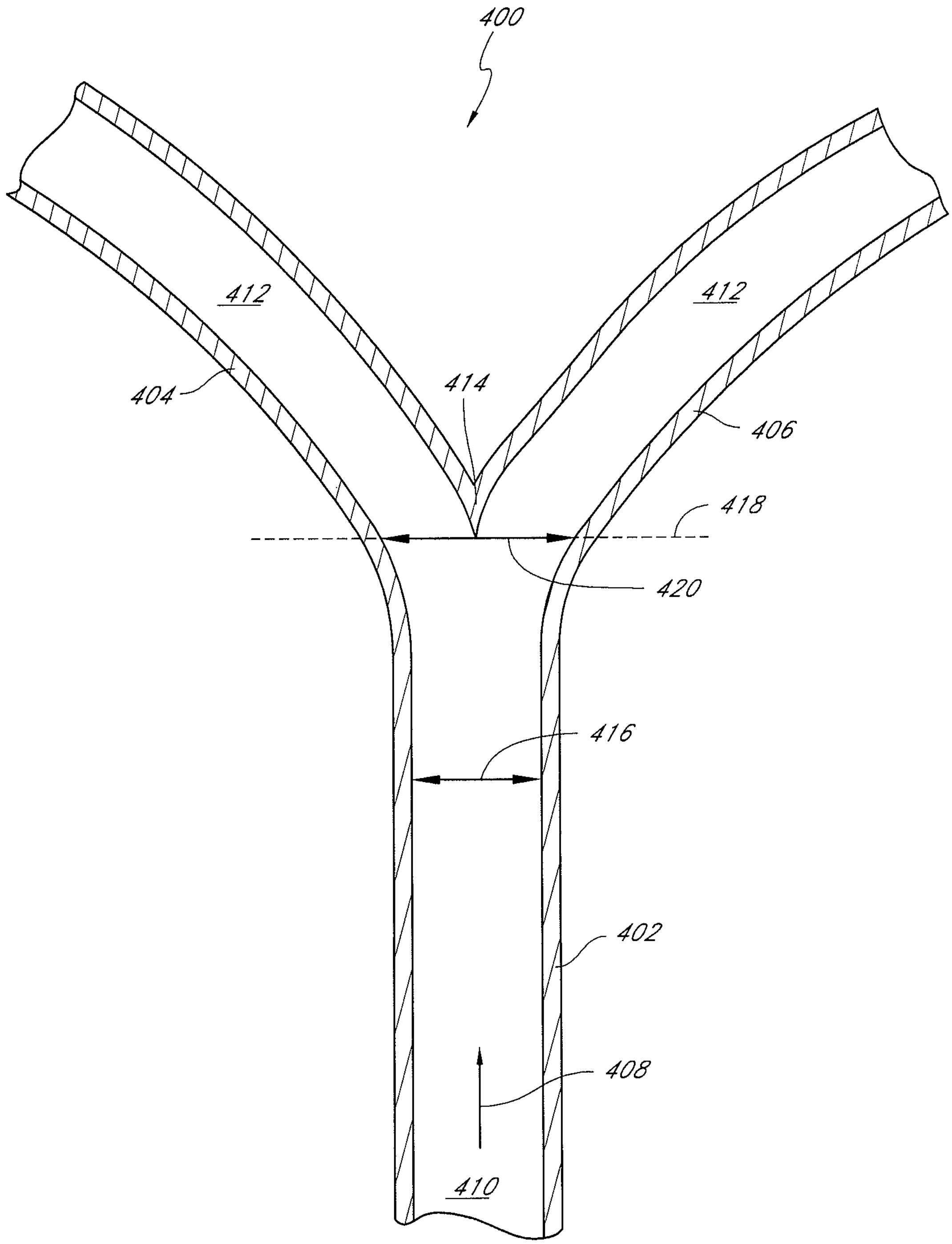

FIG. 25

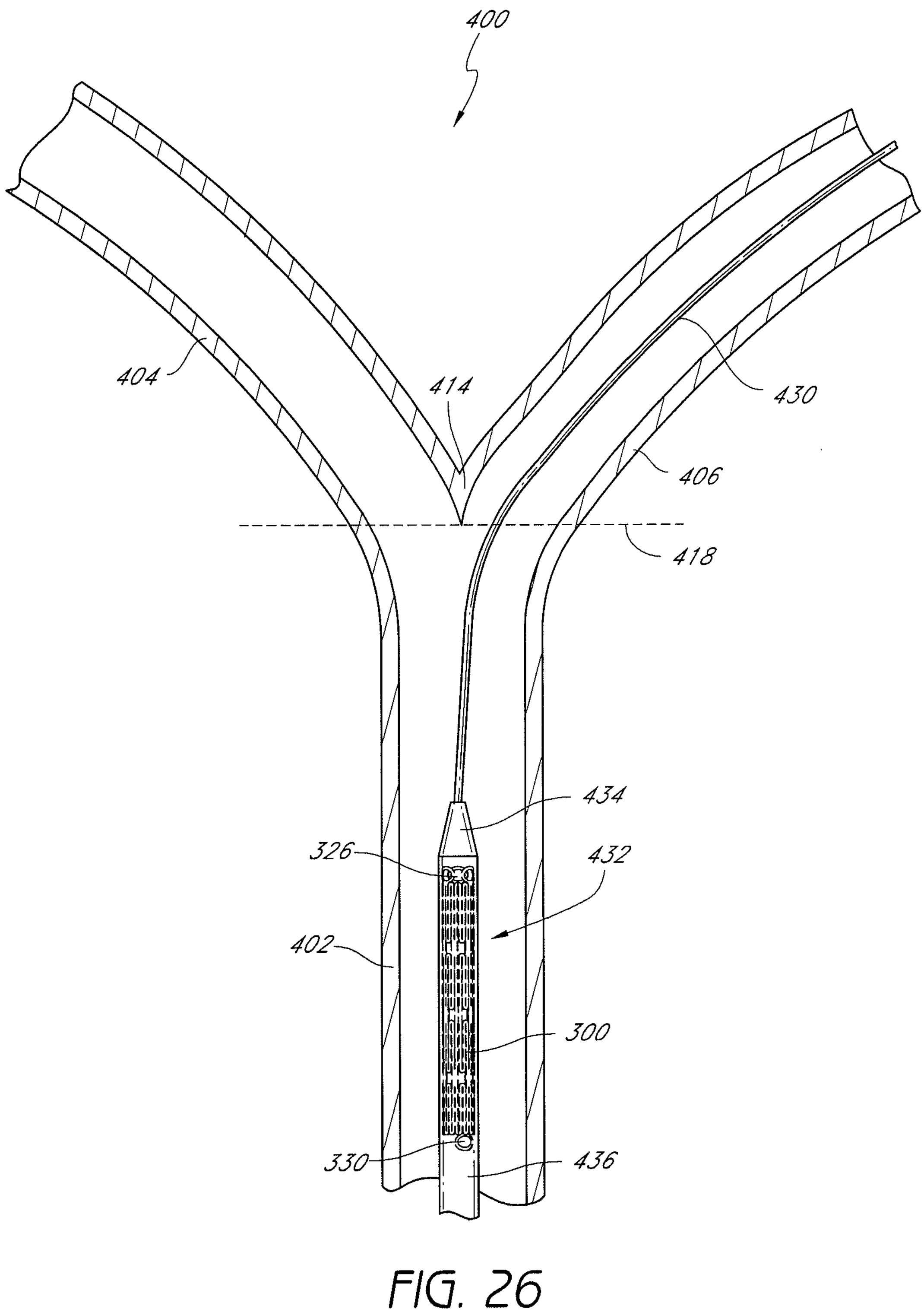

FIG. 26

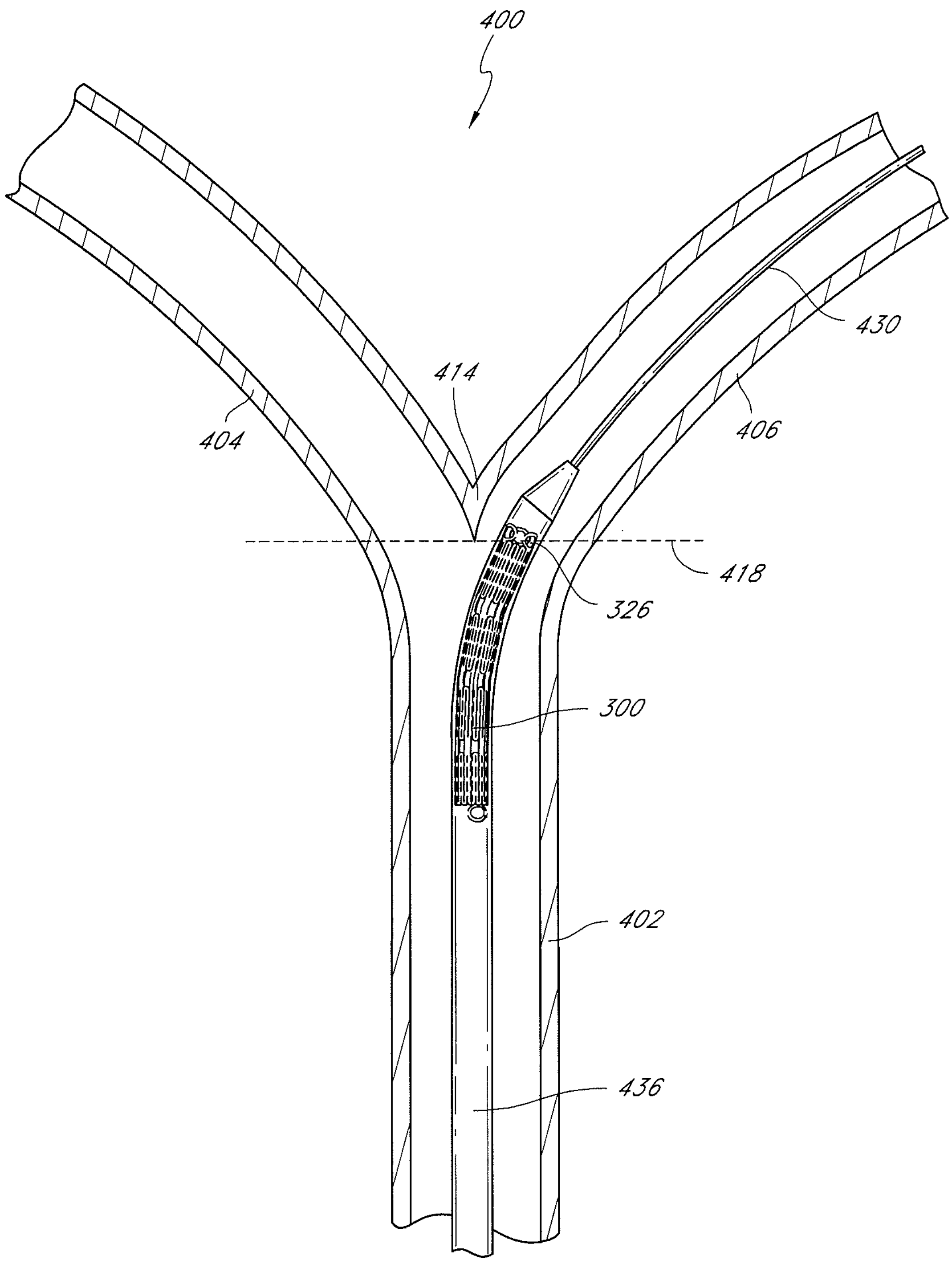

FIG. 27

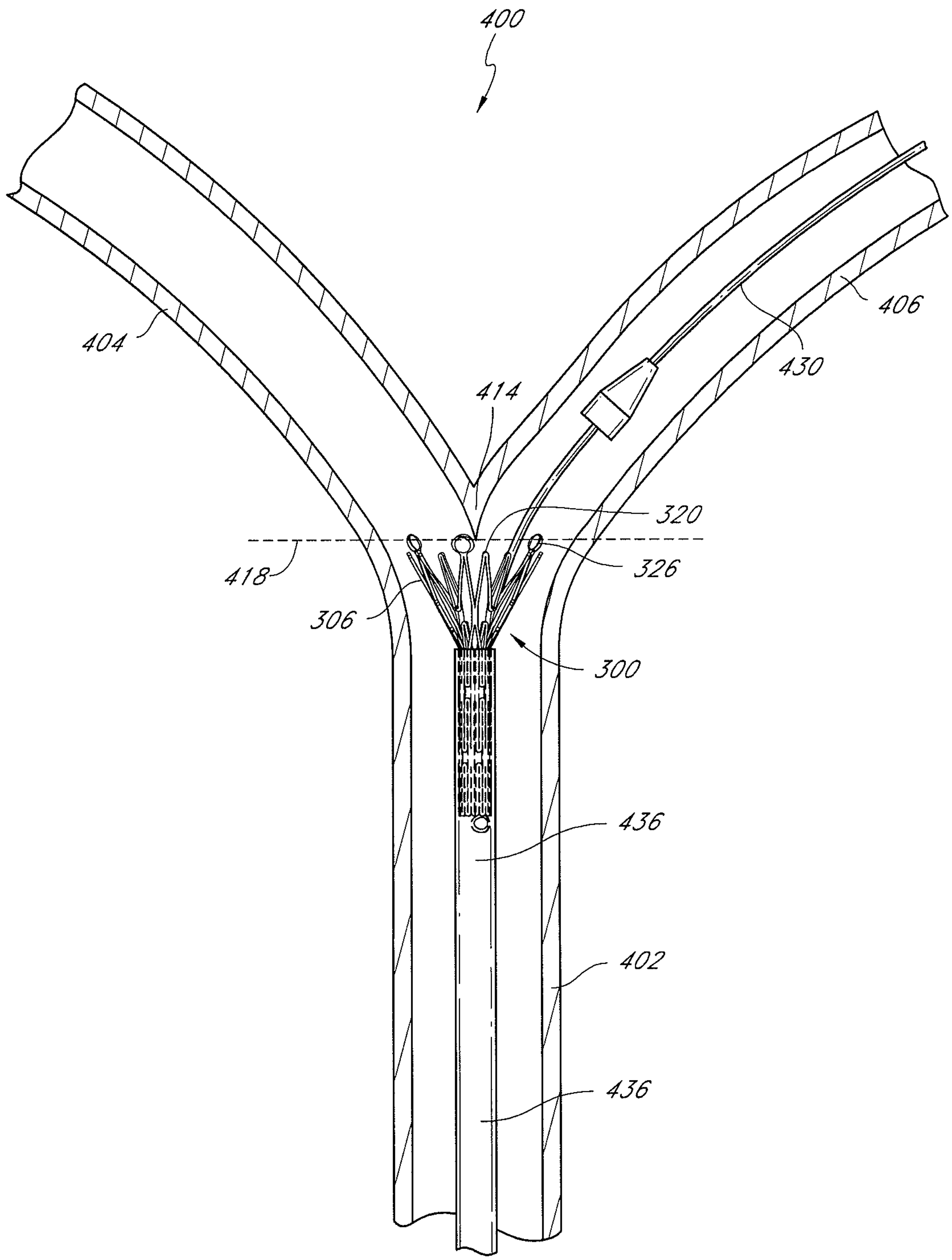

FIG. 28

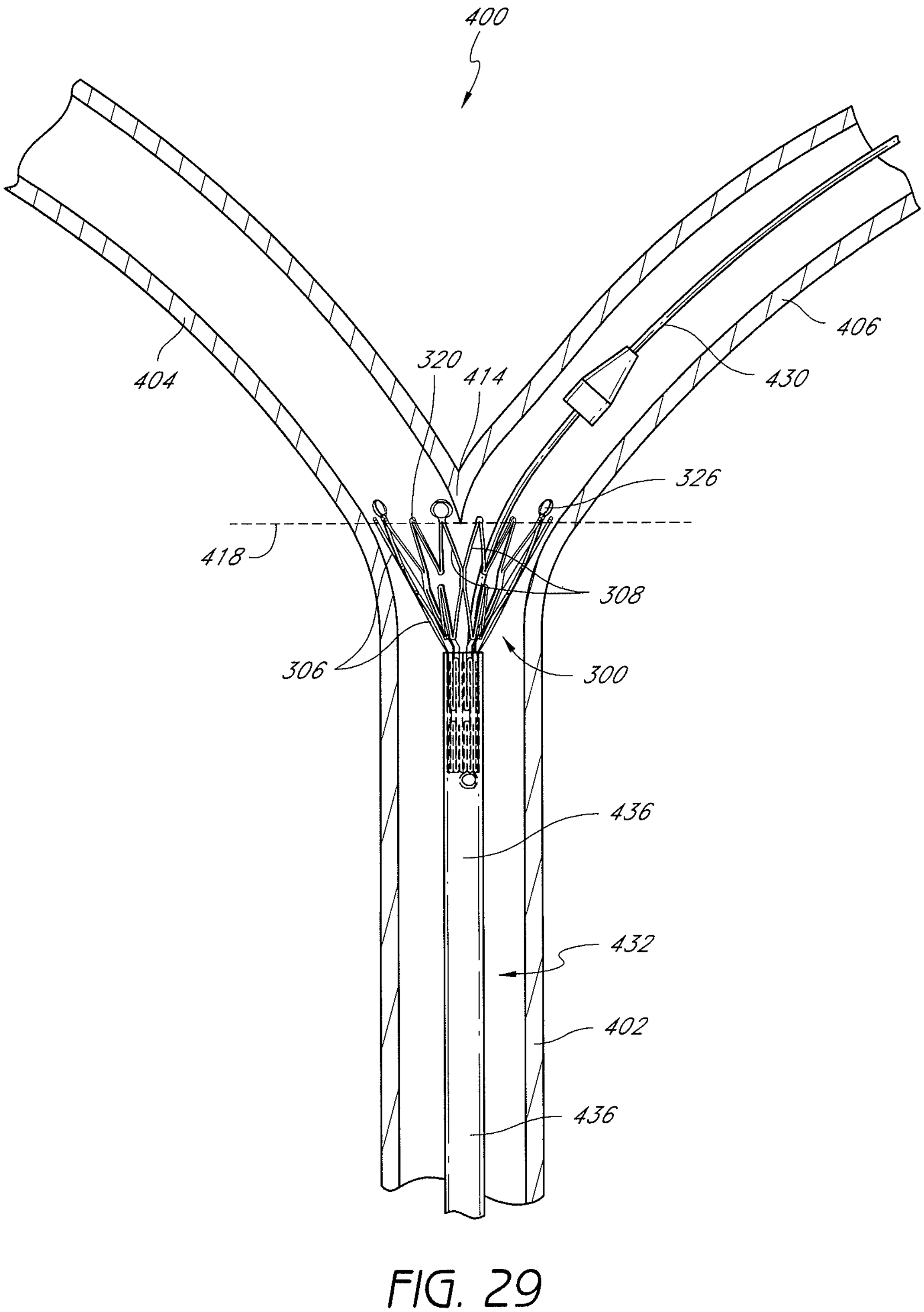

FIG. 29

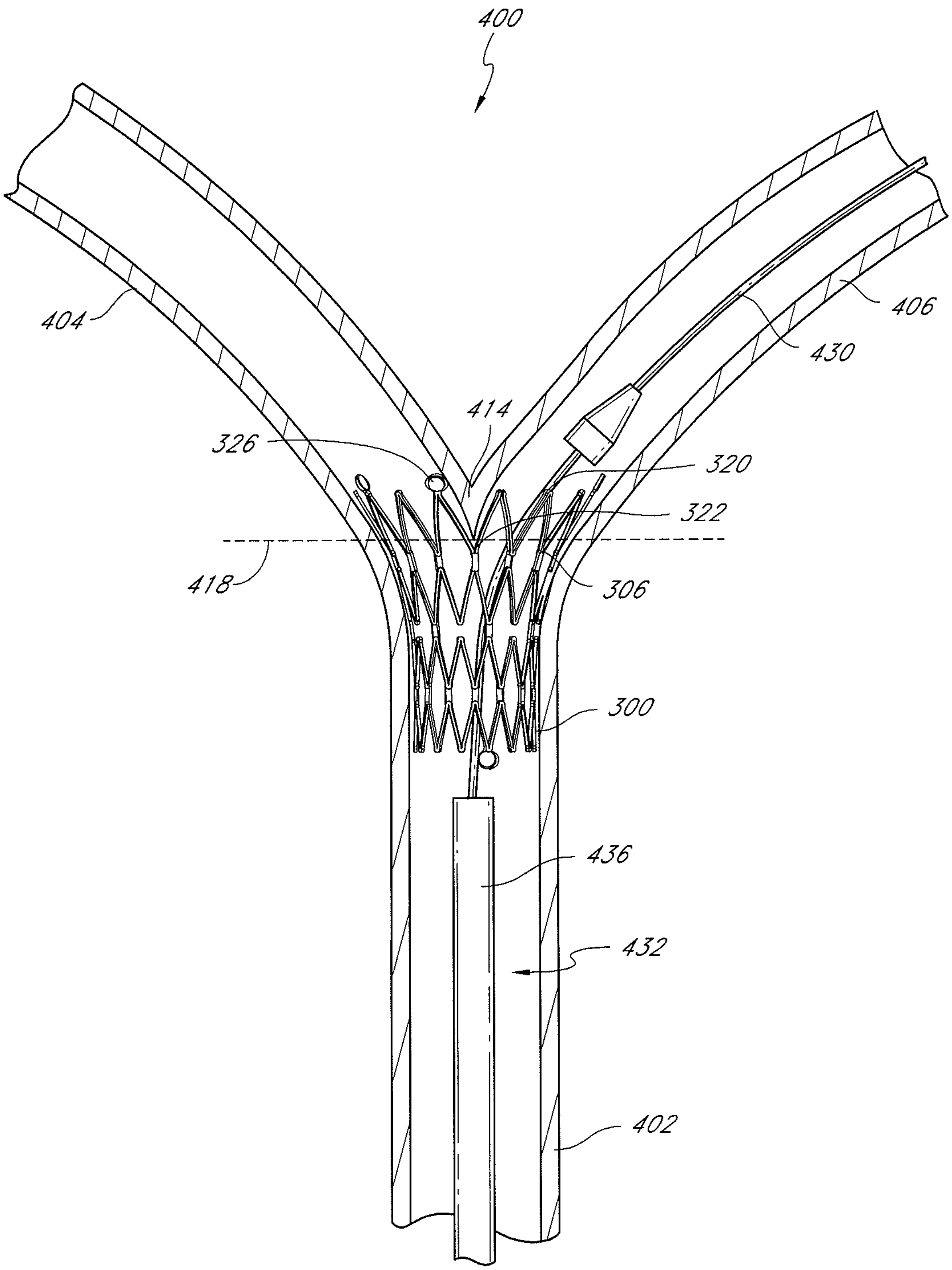

FIG. 30

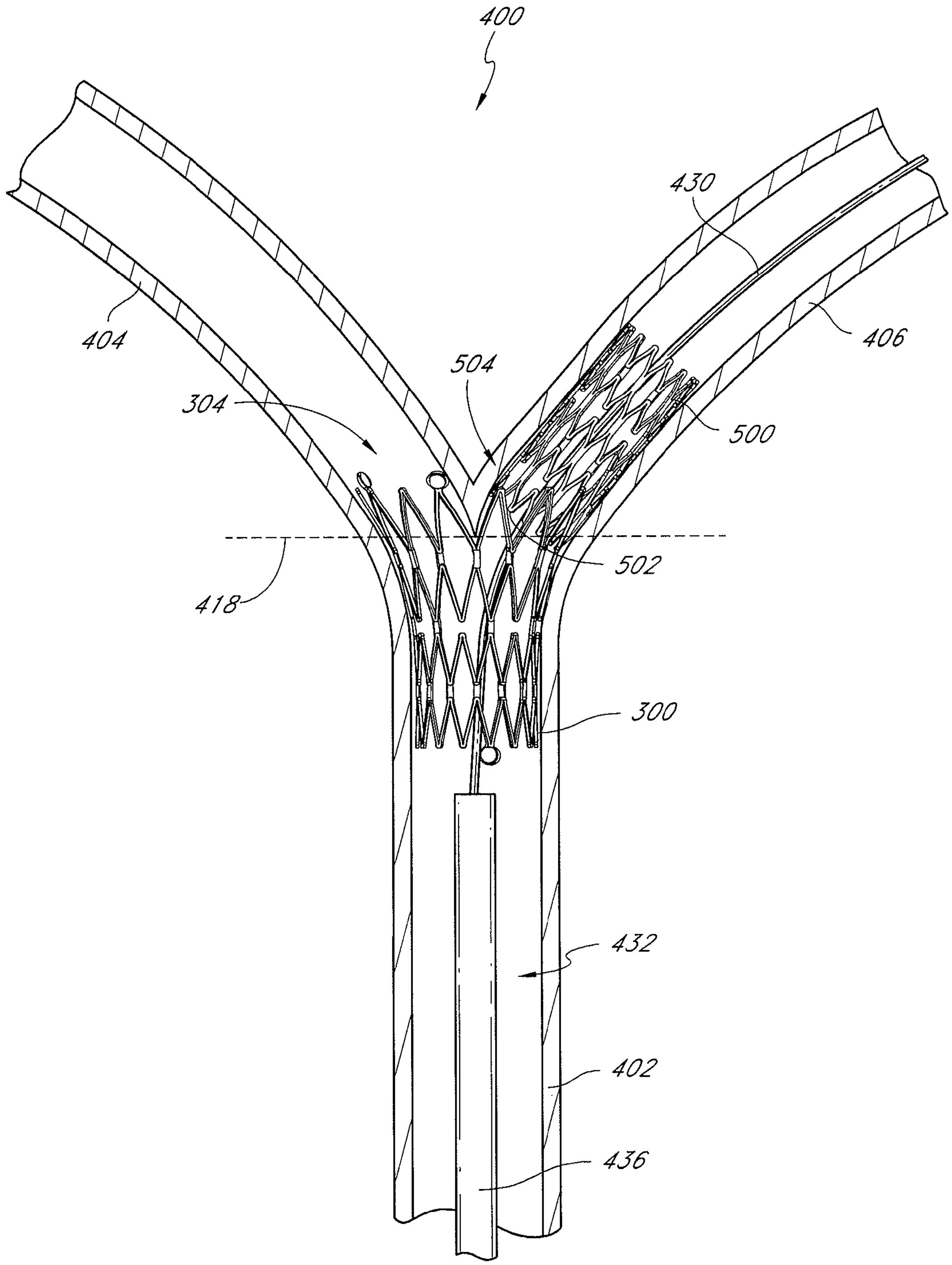

FIG. 31

BIFURCATION STENT AND METHOD OF POSITIONING IN A BODY LUMEN

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. application Ser. No. 11/737,652, filed Apr. 19, 2007, now U.S. Pat. No. 7,686,846, which is a continuation-in-part of U.S. application Ser. No. 10/225,484, filed Aug. 20, 2002, now U.S. Pat. No. 7,238, 197, which is a continuation-in-part of U.S. application Ser. No. 09/580,597, filed May 30, 2000, now U.S. Pat. No. 6,666, 883, which is a continuation-in-part of U.S. application Ser. No. 09/011,214, filed Apr. 3, 1998, now U.S. Pat. No. 6,068, 655, which is the national stage of International Application No. PCT/FR97/00999, filed Jun. 5, 1997, which claims priority from French Application No. 2749500, filed Jun. 6, 1996, the disclosures of which are all incorporated by reference in their entireties.

BACKGROUND

1. Field

The present invention relates to an apparatus permitting the treatment of bodily conduits, typically blood vessels, in an area of a bifurcation, e.g., in an area where a principal conduit separates into two secondary conduits. It also relates to equipment and methods for positioning the apparatus.

2. Description of the Related Art

It is known to treat narrowing of a rectilinear blood vessel by means of a radially expandable tubular device, commonly referred to as a stent. This stent is introduced in the unexpanded state into the internal lumen of the vessel, in particular by the percutaneous route, as far as the area of narrowing. Once in place, the stent is expanded in such a way as to support the vessel wall and thus re-establish the appropriate cross section of the vessel.

Stent devices can be made of a non-elastic material, in which case the stent is expanded by an inflatable balloon on which it is engaged. Alternatively, the stent can be self-expanding, e.g., made of an elastic material. A self-expanding stent typically expands spontaneously when withdrawn from a sheath which holds it in a contracted state.

For example, U.S. Pat. Nos. 4,733,065 and 4,806,062, which are incorporated by reference herein, illustrate existing stent devices and corresponding positioning techniques.

A conventional stent is not entirely suitable for the treatment of a narrowing situated in the area of a bifurcation, since its engagement both in the principal conduit and in one of the secondary conduits can cause immediate or delayed occlusion of the other secondary conduit.

It is known to reinforce a vascular bifurcation by means of a stent comprising first and second elements, each formed by helical winding of a metal filament. The first of the two elements has a first part having a diameter corresponding to the diameter of the principal vessel, and a second part having a diameter corresponding to the diameter of a first one of the secondary vessels. The first element is intended to be engaged in the principal vessel and the second element is intended to be engaged in the first secondary vessel. The second element has a diameter corresponding to the diameter of the second secondary vessel. After the first element has been put into place, the second element is then coupled to the first element by engaging one or more of its turns in the turns of the first element.

This equipment permits reinforcement of the bifurcation but appears unsuitable for treating a vascular narrowing or an occlusive lesion, in view of its structure and of the low possibility of radial expansion of its two constituent elements.

Moreover, the shape of the first element does not correspond to the shape of a bifurcation, which has a widened transitional zone between the end of the principal vessel and the ends of the secondary vessels. Thus, this equipment does not make it possible to fully support this wall or to treat a dissection in the area of this wall. Additionally, the separate positioning of these two elements is quite difficult.

SUMMARY

A method of deploying a bifurcation stent at a vascular bifurcation of a main vessel into first and second branch vessels includes positioning a bifurcation stent at a vascular bifurcation, the bifurcation stent expandable from a reduced diameter to an expanded diameter, the bifurcation stent comprising a first end, a second end, and a marker near the first end, wherein the first end diameter is larger than the second end diameter when the bifurcation stent is expanded, and wherein the bifurcation stent is positioned such that the marker is aligned with a carinal plane at the vascular bifurcation; partially expanding the first end of the bifurcation stent; adjusting the position of the bifurcation stent such that the marker is positioned past the carinal plane and towards the first branch vessel; and deploying the bifurcation stent at the bifurcation.

In one embodiment, the stent is self expandable. In another embodiment, the method further includes dilating the vascular bifurcation with a dilation balloon prior to said positioning, expanding the first end of the bifurcation stent with a dilation balloon after said deploying, delivering a branch stent to the first branch vessel, and/or delivering a second branch stent to the second branch vessel. In some embodiments, the branch stent is deployed such that it partially overlaps a portion of the bifurcation stent.

In one embodiment, the vascular bifurcation is selected from the group consisting of one or more of a coronary artery, a carotid artery, a femoral artery, an iliac artery, a popliteal artery, and a renal artery. In another embodiment, partially expanding the first end includes partially retracting a sheath that surrounds the bifurcation stent. The sheath can include one or more retaining bands.

In another embodiment, a method of deploying a stent at a bifurcation of a main vessel to two branch vessels, the two branch vessels forming a carina at the bifurcation, includes: partially deploying a stent at the bifurcation; advancing the stent towards the branch vessels so the stent at least partially straddles the carina; and deploying the stent at the bifurcation. The method can further include expanding a balloon at the bifurcation.

In another embodiment, a bifurcation stent includes: a plurality of cells extending along a longitudinal axis of the bifurcation stent from a first end to a second end of the bifurcation stent, each cell having a plurality of struts extending in a substantially linear, zig-zag pattern extending around the bifurcation stent, wherein the bifurcation stent is expandable from reduced diameter to an expanded diameter, the first end of the bifurcation stent having a larger diameter than the second end when expanded; and an eyelet integrally formed with the cell positioned adjacent the first end, and configured to receive a radiopaque marker therein.

In some embodiments, the bifurcation stent also includes a radiopaque marker, which can be mushroom-shaped. In some embodiments, the radiopaque marker is press-fit into the eyelet. The radiopaque marker can include gold or tantalum. In some embodiments, the radiopaque marker is selected to have

an electromotive force to match the stent. In one embodiment, the bifurcation stent also includes a second eyelet integrally formed with the cell positioned adjacent the second end and configured to receive a second radiopaque marker therein.

BRIEF DESCRIPTION OF THE DRAWINGS

Having thus summarized the general nature of the invention, certain preferred embodiments and modifications thereof will become apparent to those skilled in the art from the detailed description herein having reference to the attached figures, of which:

FIG. **1** is a side view of a first embodiment of a stent system shown in an expanded state;

FIG. **2** is a perspective, partial cutaway view of the stent system of FIG. **1** shown in a state of radial contraction, as disposed on a delivery catheter;

FIG. **3** is a longitudinal sectional view of a bifurcation treatable by the stent system of FIG. **1**;

FIG. **4** is a section view of the bifurcation of FIG. **3** showing a delivery catheter positioned therein;

FIG. **5** is a section view of the bifurcation of FIG. **3** showing an embodiment of a stent system shown in a partially contracted state on a portion of a delivery catheter;

FIG. **6** is a section view of the bifurcation of FIG. **3** showing an embodiment of a stent system shown in an expanded and fully deployed state;

FIG. **7** is a section view of a bifurcation presenting an aneurysm and an embodiment of a stent system shown deployed therein,

FIG. **8** is a side view of a stent system according to a second embodiment shown in an expanded state;

FIG. **9** is a plan view of a delivery catheter usable to deploy a stent system having certain features and advantages;

FIG. **9**A is an alternative embodiment of a proximal handpiece of the delivery catheter of FIG. **9**;

FIG. **9**B is an alternative embodiment of the delivery catheter of FIG. **9**;

FIG. **9**C is a section view of a portion of the delivery catheter of FIG. **9** taken through line **9**C-**9**C and specifically showing an alternative pull wire lumen;

FIG. **9**D is a section view of a portion of the delivery catheter of FIG. **9** taken through line **9**D-**9**D and specifically showing a retaining band;

FIG. **9**E is a detail view of a retraction band retention assembly of the delivery catheter of FIG. **9**;

FIG. **10** is a partial cutaway view of a distal portion of the catheter of FIG. **9** including a stent system disposed thereon;

FIG. **10**A is an alternative embodiment of a distal end assembly of the delivery catheter of FIG. **9**B;

FIG. **10**B is a detail view of a distal portion of the outer sheath shown in FIG. **10**;

FIG. **10**C is a section view taken along the line **10**C-**10**C of FIG. **10**;

FIG. **11**A is a plan view of a transitional portion of the catheter of FIG. **9**;

FIG. **11**B is a cross sectional view of the transitional portion taken along the line **11**B-**11**B of FIG. **11**A;

FIG. **11**C is a transverse sectional view of the transitional portion taken along the line **11**C-**11**C of FIG. **11**A;

FIG. **11**D is a cross sectional view of the proximal shaft taken along the line **11**D-**11**D of FIG. **11**A;

FIG. **12** is a side section view of a distal portion of an embodiment of a delivery catheter having certain features and advantages;

FIG. **13** is a section view of a bifurcation showing an embodiment of a delivery catheter positioned therein;

FIG. **14** is a section view of a bifurcation showing a first stent in a partially deployed state;

FIG. **15** is a section view of a bifurcation showing a first stent in a fully deployed state;

FIG. **16** is a section view of a bifurcation showing a second stent in a partially deployed state;

FIG. **17** is a section view of a bifurcation showing a second stent in a fully deployed state;

FIG. **18** is a section view of a bifurcation as in FIG. **17**, with a second branch stent deployed in the second branch;

FIG. **19** is a schematic elevation view of a single-stent delivery system for delivering a cylindrical stent;

FIG. **20** is a schematic elevation view of the single-stent delivery system of FIG. **19** showing the sheath in a proximal detail view;

FIG. **21** is a schematic elevation view of a single-stent delivery system for delivering a conical stent;

FIG. **22** is a schematic elevation view of the single-stent delivery system of FIG. **21** showing the sheath in a proximal detail view;

FIG. **23**A is a side view of a tapered bifurcation stent in accordance with one embodiment of the present invention;

FIG. **23**B is the sidewall pattern of the bifurcation stent of FIG. **23**A shown in a compressed orientation;

FIG. **23**C is a side view of an alternate tapered stent of the present invention.

FIG. **23**D is an enlarged view of a marker retention band;

FIG. **23**E is a side elevational view of a marker prior to mounting in a marker retention band;

FIG. **23**F is a perspective view of a mounted marker in a stent of the present invention.

FIG. **24**A is a side view of a tapered bifurcation stent in accordance with another embodiment of the present invention;

FIG. **24**B is the sidewall pattern of the bifurcation stent of FIG. **24**A; and

FIGS. **25**-**31** illustrate the delivery of a bifurcation stent to a vascular bifurcation.

DETAILED DESCRIPTION

As described above, the attached Figures illustrate a stent system and corresponding delivery system for use in treating vessels (e.g., conduits) within the human body at areas of bifurcations. FIG. **3** shows a bifurcation **30** in which a main conduit or vessel **32** separates into two secondary branch conduits or vessels **34**. The stent system generally includes a pair of dissimilar stents specifically designed for use in an area of a bifurcation **30**. Such dissimilar stents are then disposed on an elongate catheter for insertion into the human body. The dissimilar stents may be self-expanding or manually expandable such as by a balloon about which the stents may be disposed as will be described in further detail below.

FIG. **1** shows one embodiment of an expandable stent system **10** permitting the treatment of bodily conduits in the area of a bifurcation such as that shown. The stent system **10**, shown in an expanded state in FIG. **1**, generally comprises first **12** and second **14** stent portions which may each be divided into two segments, thus creating four successive segments **22**, **24**, **26**, **28**, of meshwork structure. The first stent **12** is generally adapted to be disposed in a branch conduit or vessel **34** of a bifurcation, while the second stent **14** is generally adapted to be disposed in a main vessel **32** (see FIG. **3**). If desired, the segments may be connected to one another via one or more bridges of material **18**. The stents **12**, **14** are generally movable between a contracted position and an expanded position. As will be clear to those skilled in the art, the stents may be self-expanding or balloon-expandable.

According to the illustrated embodiment, the stents **12**, **14** generally comprise an expandable mesh structure which includes a plurality of mesh cells **36**. The mesh cells **36** of these segments are in one embodiment elongated in the longitudinal direction of the stents **12**, **14** and have in each case a substantially hexagonal shape in the embodiment shown. Those skilled in the art will recognize that the mesh used to form the stent segments **22**, **24**, **26**, and **28** may comprise a variety of other shapes known to be suitable for use in stents. For example a suitable stent may comprise mesh with repeating quadrilateral shapes, octagonal shapes, a series of curvatures, or any variety of shapes such that the stent is expandable to substantially hold a vessel or conduit at an enlarged inner diameter.

The first stent **12** may be divided into two segments **22** and **24** which may be identical to each other and typically have a tubular shape with a diameter which is substantially greater than the diameter of one of the secondary branch conduits **34**. Those skilled in the art will recognize that the first stent may comprise a variety of shapes such that it functions as described herein. The first stent **12** may be expandable to a substantially cylindrical shape having a constant diameter along its length. The first stent **12** may comprise a range of lengths depending on the specific desired location of placement. For example, the length of the first stent **12** will typically be between about 1 and about 4 centimeters as desired.

The second stent **14** is preferably adapted to be deployed in close proximity to the first stent **12**, and may also be divided into upper **26** and lower **28** segments. The lower segment **28** of the second stent **14** typically has a tubular cross-sectional shape and has an expanded diameter which is substantially greater than the diameter of the principal conduit **32** (FIG. **3**). The upper segment **26** of the second stent **14** preferably comprises a larger diameter at its distal (upper) end **38** than at its proximal (lower) end **40**. In one embodiment the upper segment of the second stent portion comprises a substantially conical shape. In an alternative embodiment, the second stent **14** may be tapered radially outward along its entire length in the distal direction. In either embodiment however, the expanded diameter of the distal end **38** of the second stent **14** is preferably substantially larger than the expanded diameter of the proximal end **42** of the first stent **12**. For example, the distal end **38** of the second stent **14** may expand to a diameter that is at least about 105%, and preferably at least about 110%, and in some embodiments as much as 120% or more, of the diameter of the proximal end **42** of the first stent **12**. The second stent **14** may comprise a range of lengths depending on the specific desired location of placement. For example, the second stent **14** will typically be between 1 and 4 centimeters as desired.

In its expanded state, as shown in FIG. **1**, the upper segment **26** of the second stent **14** typically has mesh cells **36** whose width increases progressively, compared to that of the meshes of the lower segment **28**, on the one hand in the longitudinal sense of the dual stent device **10**, in the direction of the distal end **38** of the second stent **14**, and, on the other hand, in the transverse sense of the second stent **14**, in the direction of a generatrix diametrically opposite that located in the continuation of the bridge **18**. Alternatively stated, the upper segment **26** of the second stent **14** preferably comprises a mesh with multiple cellular shapes **36** which may have larger dimensions at a distal end **38** of the stent **14** than those at the proximal end **40** such that the second stent **14** expands to a substantially funnel shape.

In the embodiment shown, this increase in the width of the mesh cells **36** results from an increase in the length of the edges **48** of the mesh cells **36** disposed longitudinally, as well as an increase in the angle formed between two facing edges **48**.

This segment **26** thus may have a truncated shape with an axis which is oblique in relation to the longitudinal axis of the first stent **12** when expanded. This shape, for example, corresponds to the shape of the bifurcation shown in the area of the widened transitional zone **46** (FIG. **3**) which separates the end of the principal conduit **32** (see FIG. **3**) from the ends of the secondary conduits **34**. In a preferred embodiment, the second stent **14** is placed in close proximity to the first stent **12**. For example, the distal end **38** of the second stent **14** is preferably placed within a distance of about 4 mm of the distal end **42** of the first stent **12**, more preferably this distance is less than about 2 mm, and most preferably the stents are placed within 1 mm of one another.

In the embodiment shown in FIG. **1**, the distance between first and second stents **12**, **14** is held substantially fixed by the provision of a bridge **18** between them. Bridges **18** may be provided to join the first and second stents **12**, **14** to one another and/or to join the upper and lower segments **22**, **24** and **26**, **28** of each stent **12** and **14** together. If present, the bridges **18** may connect the adjacent ends of the segments **22**, **24** and **26**, **28** and typically have a small width, so that they can undergo a certain flexion, making it possible to orient these segments in relation to one another, in particular the lower segment **24** of the first stent **12** in relation to the upper segment **26** of the second stent **14**.

In addition, in other embodiments, the bridges **18** could be integral with one of the connected segments and separately connected, such as by welding, to the other connected segment. For example, the bridge **18** which connects the first and second stents **12**, **14** could be integral with the upper segment **26** of the second stent **14** and connected to lower segment **24** of the first segment **26**. Alternatively, the bridge **18** could be integral with the lower segment **24** of the first stent **12** and connected to the upper segment **26** of the second stent **14**.

In yet other embodiments, bridges **18** could be separate pieces of materials which are separately connected to segments **22**, **24**, **26**, **28** such as by welding, adhesion, or other bonding method. In all of these embodiments, the first stent **12** can be made from different pieces of material than the second stent **14**. A tube from which the first stent **12** may be made (e.g., by laser cutting techniques) may comprise a smaller diameter than a tube from which the second stent **14** may be made. The respective tubes may or may not be made of the same material. Alternatively, the first and second stent may be formed from a single piece of material.

When the segments **26** and **28** of the second stent **14** are made from tubes of a smaller diameter than the segments **22** and **24** of the first stent **12**, the radial force of the first stent segments **22** and **24** is larger than the radial force of the second stent segments **26** and **28**, especially at larger cross sections.

Accordingly, bridges **18** can be made from one of these tubes, and thus be integral with segments **22** and **24** or segments **26** and **28**. Alternatively, the bridges **18** can be separate pieces of material.

In further embodiments, bridges **18** are omitted such that the individual segments are spaced as desired during installation and use. These individual segments are still delivered and implanted in the same core and sheath assembly.

The bridges **18** between two consecutive segments could be greater or smaller in number than six, and they could have a shape other than an omega shape, permitting their multidirectional elasticity, and in particular a V shape or W shape.

For example, FIG. **8** shows an alternative embodiment of the stent system **10** with first **12** and second **14** stents shown in their unconstrained, expanded states. According to this embodiment, each stent **12**, **14** may be divided into two segments **22**, **24** and **26**, **28** and may include one or more flexible bridges **18** connecting the first **12** and second stents **14** to one another. In this embodiment, the two consecutive segments **22**, **24** and **26**, **28** of the first and second stents **12** and **14**, are connected by a plurality (e.g., six) omega-shaped bridges **50**. The curved central part **52** of these bridges **50** may have a multidirectional elasticity permitting the appropriate longitudinal orientation of the various segments in relation to one another. The advantage of these bridges **50** is that they provide the stent with longitudinal continuity, which facilitates the passage of the stent system into a highly curved zone and which eliminates the need to reduce this curvature, (which may be dangerous in the cases of arteriosclerosis).

Thus, the stent system **10** of FIG. **8** can comprise several segments **22**, **24**, **26**, **28** placed one after the other, in order to ensure supplementary support and, if need be, to increase the hold of the stents in the bifurcation **30**. The upper segment **26** of the second stent **14** could have an axis coincident with the longitudinal axis of the first stent, and not oblique in relation to this axis, if such is rendered necessary by the anatomy of the bifurcation which is to be treated.

Alternatively, the lower segment **24** of the first stent **12** could itself have, in the expanded state, a widened shape similar to that of the second stent and corresponding to the shape of the widened connecting zone (increasing diameter in the proximal direction) by which, in certain bifurcations, the secondary conduits **34** (see FIG. **3**) are connected to the widened transition zone **46**. Thus, the lower segment **24** of the first stent **12**, or the entire first stent **12** may have a first diameter at its distal end, and a second, larger diameter at its proximal end with a linear or progressive curve (flared) taper in between. According to this embodiment, this segment **24** would thus have a shape corresponding to the shape of this widened connecting zone, and would ensure perfect support thereof.

One method of making a self-expanding stent is by appropriate cutting of a sheet of nickel/titanium alloy (for example, an alloy known by the name NITINOL may appropriately be used) into a basic shape, then rolling the resulting blank into a tubular form. The blank may be held in a cylindrical or frustroconical form by welding the opposing edges of this blank which come into proximity with each other. The stent(s) may also be formed by laser cutting from metal tube stock as is known in the art. Alternatively, a stent may be formed by selectively bending and forming a suitable cylindrical or noncylindrical tubular shape from a single or multiple wires, or thin strip of a suitable elastic material. Those skilled in the art will understand that many methods and materials are available for forming stents, only some of which are described herein.

Some Nickel Titanium alloys are malleable at a temperature of the order of 10° C. but can recover a neutral shape at a temperature substantially corresponding to that of the human body. FIG. **2** shows the stent system **10** (see FIG. **1**) disposed on a delivery catheter in a state of radial contraction. In one embodiment, a self-expanding stent may be contracted by cooling its constituent material of nickel-titanium or other shape-memory alloy to a temperature below its transformation temperature. The stent may later be expanded by exposing it to a temperature above the transformation temperature. In the present use, a shape-memory alloy with a transformation temperature at or below normal body temperature may be used. Those skilled in the art will recognize that a self-expanding stent made of a substantially elastic material may also be mechanically contracted from its expanded shape by applying a radial compressive force. The stent may then be allowed to expand under the influence of the material's own elasticity. Nickel titanium and other alloys such as such as Silver-Cadmium (Ag—Cd), Gold-Cadmium (Au—Cd) and Iron-Platinum (Fe_3—Pt), to name but a few offer desirable superelastic qualities within a specific temperature range.

In one embodiment, the contraction of a stent may cause the mesh cell edges **48** to pivot in relation to the transverse edges **49** of the mesh cells **36** (see FIG. **3**) in such a way that the mesh cells **36** have, in this state of contraction, a substantially rectangular shape. Those skilled in the art will recognize that other materials and methods of manufacturing may be employed to create a suitable self-expanding stent.

Alternatively, the stents used may be manually expandable by use of an inflatable dilatation balloon with or without perfusion as will be discussed further below. Many methods of making balloon-expandable stents are known to those skilled in the art. Balloon expandable stents may be made of a variety of bio-compatible materials having desirable mechanical properties such as stainless steel and titanium alloys. Balloon-expandable stents preferably have sufficient radial stiffness in their expanded state that they will hold the vessel wall at the desired diameter. In the case of a balloon-expandable second stent **14**, the balloon on which the second stent **14** is disposed may be specifically adapted to conform to the desired shape of the second stent **14**. Specifically, such a balloon will preferably have a larger diameter at a distal end than at a proximal end.

The present discussion thus provides a pair of dissimilar stents permitting the treatment of a pathological condition in the area of a bifurcation **30**. This system has the many advantages indicated above, in particular those of ensuring a perfect support of the vessel wall and of being relatively simple to position.

For the sake of simplification, the segment which has, in the unconstrained expanded state, a cross section substantially greater than the cross section of one of the secondary conduits will be referred to hereinafter as the "secondary segment", while the segment which has, in the expanded state, a truncated shape will be referred to hereinafter as the "truncated segment."

The secondary segment is intended to be introduced into the secondary conduit in the contracted state and when expanded will preferably bear against the wall of the conduit. This expansion not only makes it possible to treat a narrowing or a dissection situated in the area of the conduit, but also to ensure perfect immobilization of the apparatus in the conduit.

In this position, the truncated segment bears against the wall of the conduit delimiting the widened transitional zone of the bifurcation, which it is able to support fully. A narrowing or a dissection occurring at this site can thus be treated by means of this apparatus, with uniform support of the vascular wall, and thus without risk of this wall being damaged.

The two segments may be adapted to orient themselves suitably in relation to each other upon their expansion.

Advantageously, at least the truncated segment may be covered by a membrane (for example, DACRON® or ePTFE) which gives it impermeability in a radial direction. This membrane makes it possible to trap between it and the wall of the conduit, the particles which may originate from the lesion being treated, such as arteriosclerotic particles or cellular agglomerates, thus avoiding the migration of these particles in the body. Thus, the apparatus can additionally permit treatment of an aneurysm by guiding the liquid through the bifurcation and thereby preventing stressing of the wall forming the aneurysm.

The segments can be made from tubes of material of a different diameter, as discussed above, with the tube for the truncated segment having a larger diameter than the tube for the secondary segment. The tubes may be made from the same material. The use of tubes of different diameters can result in the truncated segment having a larger radial force, especially at larger diameters.

The apparatus can comprise several secondary segments, placed one after the other, to ensure supplementary support of the wall of the secondary conduit and, if need be, to increase the anchoring force of the stent in the bifurcation. To this same end, the apparatus can comprise, on that side of the truncated segment directed toward the principal conduit, at least one radially expandable segment having, in the expanded state, a cross section which is substantially greater than the cross section of the principal conduit.

These various supplementary segments may or may not be connected to each other and to the two aforementioned segments by means of flexible links, such as those indicated above.

The flexible links can be integral with one of the segments and separately connected to the other segment, or the flexible links can be separate pieces of material separately connected to both segments, such as by welding.

Preferably, the flexible link between two consecutive segments is made up of one or more bridges of material connecting the two adjacent ends of these two segments. Said bridge or bridges are advantageously made of the same material as that forming the segments.

Each segment may have a meshwork structure, the meshes being elongated in the longitudinal direction of the stent, and each one having a substantially hexagonal shape; the meshes of the truncated segment may have a width which increases progressively in the longitudinal sense of the stent, in the direction of the end of this segment having the greatest cross section in the expanded state.

This increase in the width of the meshes is the result of an increase in the length of the edges of the meshes disposed longitudinally and/or an increase in the angle formed between two facing edges of the same mesh.

In addition, the truncated segment can have an axis not coincident with the longitudinal axis of the secondary segment, but oblique in relation to this axis, in order to be adapted optimally to the anatomy of the bifurcation which is to be treated. In this case, the widths of the meshes of the truncated segment also increase progressively, in the transverse sense of the stent, in the direction of a generatrix diametrically opposite that located in the continuation of the bridge connecting this segment to the adjacent segment.

The apparatus can be made of a metal with shape memory, which becomes malleable, without elasticity, at a temperature markedly lower than that of the human body, in order to permit retraction of the apparatus upon itself, and to allow it to recover its neutral shape at a temperature substantially corresponding to that of the human body. This metal may be a nickel/titanium alloy known by the name NITINOL.

The deployment catheter for positioning the stent or stents comprises means for positioning the stents and means for permitting the expansion of the stents when the latter are in place. These means can comprise a catheter having a removable sheath in which the stent is placed in the contracted state, when this stent is made of an elastic material, or a support core comprising an inflatable balloon on which the stent is placed, when this stent is made of a nonelastic material.

In either case, this equipment comprises, according to the invention, means with which it is possible to identify and access, through the body of the patient, the longitudinal location of the truncated segment, so that the latter can be correctly positioned in the area of the widened zone of the bifurcation.

In the case where the expansion of this same segment is not uniform in relation to the axis of the stent, the equipment additionally comprises means with which it is possible to identify, through the body of the patient, the angular orientation of the stent in relation to the bifurcation to be treated, so that the part of this segment having the greatest expansion can be placed in a suitable manner in relation to the bifurcation.

Referring to FIG. **9**, the stent system is generally deployed using an elongate flexible stent deployment catheter **100**. Although primarily described in the context of a multiple stent placement catheter without additional functional capabilities, the stent deployment catheter described herein can readily be modified to incorporate additional features such as an angioplasty balloon or balloons, with or without perfusion conduits, radiation or drug delivery capabilities, or stent sizing features, or be simplified to deploy only a single stent, or any combination of these features.

The elongate delivery catheter **100** generally includes a proximal end assembly **102**, a proximal shaft section **110** including a tubular body **111**, a distal shaft section **120** including a distal tubular body **113**, and a distal end assembly **107**. The proximal end **102** may include a handpiece **140** (see FIG. **9**B), having one or more hemostatic valves and/or access ports **106**, such as for the infusion of drugs, contrast media or inflation media in a balloon expandable stent embodiment, as will be understood by those of skill in the art. In addition, a proximal guidewire port **172** may be provided on the handpiece **140** in an over the wire embodiment (see FIG. **9**A). The handpiece **140** (see FIG. **9**B) disposed at the proximal end of the catheter **100** may also be adapted to control deployment of the stents disposed on the catheter distal end **107** as will be discussed.

The length of the catheter depends upon the desired application. For example, lengths in the area of about 120 cm to about 140 cm are typical for use in coronary applications reached from a femoral artery access. Intracranial or lower carotid artery applications may call for a different catheter shaft length depending upon the vascular access site, as will be apparent to those of skill in the art.

The catheter **100** preferably has as small an outside diameter as possible to minimize the overall outside diameter (e.g., crossing profile) of the delivery catheter, while at the same time providing sufficient column strength to permit distal transluminal advancement of the tapered tip **122** (see FIG. **9**). The catheter **100** also preferably has sufficient column strength to allow an outer, axially moveable sheath **114** (see FIG. **5**) to be proximally retracted relative to the central core **112** (see FIG. **7**) in order to expose the stents **118** (see FIG. **12**). The delivery catheter **100** may be provided in either "over-the-wire" or "rapid exchange" types as will be discussed further below, and as will generally be understood by those skilled in the art.

In a catheter intended for peripheral vascular applications, the outer sheath **114** (see FIG. **5**) will typically have an outside diameter within the range of from about 0.065 inches to about 0.092 inches. In coronary vascular applications, the outer sheath **114** (see FIG. **5**) may have an outside diameter with the range of from about 0.039 inches to about 0.065. Diameters outside of the preferred ranges may also be used, provided that the functional consequences of the diameter are acceptable for the intended purpose of the catheter. For example, the lower limit of the diameter for any portion of catheter **100** in a given application will be a function of the number of guidewire, pullwire or other functional lumen contained in the catheter, together with the acceptable minimum flow rate of dilatation fluid, contrast media or drugs to be delivered through the catheter and minimum contracted stent diameter.

The ability of the catheter **100** to transmit torque may also be desirable, such as to avoid kinking upon rotation, to assist in steering, and in embodiments having an asymmetrical distal end on the proximal stent **14**. The catheter **100** may be provided with any of a variety of torque and/or column strength enhancing structures, for example, axially extending stiffening wires, spiral wrapped support layers, or braided or woven reinforcement filaments which may be built into or layered on the catheter **100**. See, for example, U.S. Pat. No. 5,891,114 to Chien, et al., the disclosure of which is incorporated in its entirety herein by reference.

Referring to FIG. **11**D, there is illustrated a cross-sectional view through the proximal section **106** of the catheter shaft **100** of FIG. **9**B. The embodiment shown in FIG. **11**D represents a rapid exchange embodiment, and may comprise a single or multiple lumen extrusion or a hypotube including a pull wire lumen **220**. In an over-the-wire embodiment, the proximal section **106** additionally comprises a proximal extension of a guidewire lumen **132** and a pull wire lumen **220**. See FIG. **11**C. The proximal tube **111** may also comprise an inflation lumen in a balloon catheter embodiment as will be understood by those skilled in the art.

At the distal end **107**, the catheter is adapted to retain and deploy one or more stents within a conduit of a human body. With reference to FIGS. **10**A and **12**, the distal end assembly **107** of the delivery catheter **100** generally comprises an inner core **112** (see FIG. **7**), an axially moveable outer sheath **114** (see FIG. **5**), and optionally one or more inflatable balloons **116** (FIG. **12**). The inner core **112** (see FIG. **7**) is preferably a thin-walled tube at least partially designed to track over a guidewire, such as a standard 0.014 inch guidewire. The outer sheath **114** (see FIG. **5**) preferably extends along at least a distal portion **120** of the central core **112** (see FIG. **10**) on which the stents **118** (see FIG. **12**) are preferably disposed.

The outer sheath **114** (see FIG. **5**) may extend over a substantial length of the catheter **100**, or may comprise a relatively short length, distal to the proximal guidewire access port **172** as will be discussed. In general, the outer sheath **114** (see FIG. **5**) is between about 5 and about 25 cm long.

Referring to FIG. **10**, the illustrated outer sheath **114** comprises a proximal section **115**, a distal section **117** and a transition **119**. The proximal section **115** has an inside diameter which is slightly greater than the outside diameter of the tubular body **113**. This enables the proximal section **115** to be slideably carried by the tubular body **113**. Although the outer sheath **114** may be constructed having a uniform outside diameter throughout its length, the illustrated outer sheath **114** steps up in diameter at a transition **119**. The inside diameter of the distal section **117** of outer sheath **114** is dimensioned to slideably capture the one or more stents as described elsewhere herein. In a stepped diameter embodiment such as that illustrated in FIG. **10**, the axial length of the distal section **117** from the transition **119** to the distal end is preferably sufficient to cover the stent or stents carried by the catheter **100**. Thus, the distal section **117** in a two stent embodiment is generally at least about 3 cm and often within the range of from about 5 cm to about 10 cm in length. The axial length of the proximal section **115** can be varied considerably, depending upon the desired performance characteristics. For example, proximal section **115** may be as short as one or two centimeters, or up to as long as at least about 75% or 90% or more of the entire length of the catheter. In the illustrated embodiment, the proximal section **115** is generally within the range of from about 5 cm to about 15 cm long.

The outer sheath **114** and inner core **112** may be produced in accordance with any of a variety of known techniques for manufacturing rapid exchange or over the wire catheter bodies, such as by extrusion of appropriate biocompatible polymeric materials. Known materials for this application include high and medium density polyethylenes, polytetrafluoroethylene, nylons, PEBAX, PEEK, and a variety of others such as those disclosed in U.S. Pat. No. 5,499,973 to Saab, the disclosure of which is incorporated in its entirety herein by reference. Alternatively, at least a proximal portion or all of the length of central core **112** and/or outer sheath **114** may comprise a metal or polymeric spring coil, solid walled hypodermic needle tubing, or braided reinforced wall, as is understood in the catheter and guidewire arts.

The distal portion **117** of outer sheath **114** is positioned concentrically over the stents **118** (see FIG. **12**) in order to hold them in their contracted state. As such, the distal portion **117** of the outer sheath **114** is one form of a releasable restraint. The releasable restraint preferably comprises sufficient radial strength that it can resist deformation under the radial outward bias of a self-expanding stent. The distal portion **117** of the outer sheath **114** may comprise a variety of structures, including a spring coil, solid walled hypodermic needle tubing, banded, or braided reinforced wall to add radial strength as well as column strength to that portion of the outer sheath **114**. Alternatively, the releasable restraint may comprise other elements such as water soluble adhesives or other materials such that once the stents are exposed to the fluid environment and/or the temperature of the blood stream, the restraint material will dissolve, thus releasing the self-expandable stents. A wide variety of biomaterials which are absorbable in an aqueous environment over different time intervals are known including a variety of compounds in the polyglycolic acid family, as will be understood by those of skill in the art. In yet another embodiment, a releasable restraint may comprise a plurality of longitudinal axial members disposed about the circumference of the stents. According to this embodiment anywhere from one to ten or more axial members may be used to provide a releasable restraint. The axial members may comprise cylindrical rods, flat or curved bars, or any other shape determined to be suitable.

In some situations, self expanding stents will tend to embed themselves in the inner wall of the outer sheath **114** (see FIG. **5**) over time. As illustrated in FIGS. **9**D and **10**A, a plurality of expansion limiting bands **121** may be provided to surround sections of the stents **12**, **14** (see FIG. **6**) in order to prevent the stents from becoming embedded in the material of the sheath **114** (see FIG. **5**). The bands **121** may be provided in any of a variety of numbers or positions depending upon the stent design. FIG. **10**A illustrates the bands positioned at midpoints of each of the four proximal stent sections **127** and each of the five distal stent sections. In an alternative embodiment, the bands **121** are positioned over the ends of adjacent stent sections. The bands **121** may be made of stainless steel, or any other suitable metal or relatively non compliant polymer. Of course, many other structures may also be employed to prevent the self-expanding stents from embedding themselves in the plastic sheath. Such alternative structures may include a flexible coil, a braided tube, a solid-walled tube, or other restraint structures which will be apparent to those skilled in the art in view of the disclosure herein.

The inner surface of the outer sheath **114** (see FIG. **10**), and/or the outer surface of the central core **112** (see FIG. **10**) may be further provided with a lubricious coating or lining such as Paralene, Teflon, silicone, polyimide-polytetrafluoroethylene composite materials or others known in the art and suitable depending upon the material of the outer sheath **114** and/or central core **112** (see FIG. **10**).

FIG. **10**B shows a distal portion of sheath **114** received in an annular recess **230** in the distal tip. As shown, at least the distal portion of the sheath **114** may comprise a two layer construction having an outer tube **213** and an inner tube or coating **212**. The exterior surface of the outer tube **213** is preferably adapted to slide easily within the vessels to be treated, while the inner surface is generally adapted to have a low coefficient of static friction with respect to the stents, thus allowing the sheath to slide smoothly over the stents. The outer tube **213** may, for example, be made of or coated with HDPE or PEBAX, and the inner tube **212** may, for example, be made of or coated with HDPE, PTFE, or FEP. In an embodiment in which the inner tube is made with a PTFE liner, however, the distal end **214** of the lubricious inner layer or tube **212** is preferably spaced proximally from the distal end **216** of the outer tube **213** by a distance within the range of from about 1 mm to about 3 mm. This helps prevent the stent from prematurely jumping distally out of the sheath during deployment due to the high lubricity of the PTFE surface.

FIG. **10** illustrates one embodiment of a sheath retraction system. The system illustrated generally includes a sheath pull wire **222**, a pull wire slot **224**, a sheath retraction band **226**, and an outer sheath **114**. The sheath retraction band **226** may be a tubular element thermally or adhesively bonded or otherwise secured to a portion of the outer sheath **114**. In the illustrated embodiment, the retraction band **226** comprises a section of stainless steel tubing having an outside diameter of about 0.055 inches, a wall thickness of about 0.0015 inches and an axial length of 0.060 inches. However, other dimensions may be readily utilized while still accomplishing the intended function. The sheath retraction band **226** is positioned within the distal portion **117** of the outer sheath **114**, just distally of the diameter transition **119**. The retraction band **226** may be connected to the interior surface of the outer sheath **114** by heat fusing a pair of bands **225** (see FIG. **9**E) to the inside surface of the outer sheath at each end of the retraction band. Alternatively, the retraction band **226** can be attached to the outer sheath by using adhesives, epoxies, or by mechanical methods such as crimping and swaging or a combination of these. In this manner, the pull force which would be required to proximally dislodge the retraction band **226** from the outer sheath **114** is greatly in excess of the proximal traction which will be applied to the pull wire **222** in clinical use. The distal end of the pull wire **222** is preferably welded, soldered, bonded, or otherwise secured to the sheath retraction band **226**. The pull wire **222** may alternatively be bonded directly to the outer sheath.

Referring to FIG. **10**, the pull wire slot **224** is preferably of sufficient length to allow the sheath **114** to be fully retracted. Thus, the pull wire slot **224** is preferably at least as long as the distance from the distal end of the stent stop **218** to the distal end of the sheath **114**. Slot lengths within the range of from about 1 cm to about 10 cm are presently contemplated for a two stent deployment system. With the sheath **114** in the distal position as shown, the pull wire slot **224** is preferably entirely covered by the proximal portion **115** of the sheath **114**. Alternatively, in an embodiment in which the proximal extension of sheath **114** extends the entire length of the catheter **100**, discussed above, sheath **114** can be directly attached to the control **150** (see FIG. **9**B), in which case a pull wire **222** and slot **224** as shown might not be used.

In yet another embodiment illustrated for example in FIGS. **9**B and **9**C, a pull wire lumen **220** (see FIG. **9**C) may terminate sufficiently proximally from the retraction band **226** that a slot as shown may not be used.

The pull wire **222** may comprise a variety of suitable profiles known to those skilled in the art, such as round, flat straight, or tapered. The diameter of a straight round pull wire **222** may be between about 0.008" and about 0.018" and in one embodiment is about 0.009". In another embodiment, the pull wire **222** has a multiple tapered profile with successively distal diameters of 0.015", 0.012", and 0.009" and a distal flat profile of 0.006"×0.012". The pull wire **222** may be made from any of a variety of suitable materials known to those skilled in the art, such as stainless steel or nitinol, and may be braided or single strand and may be coated with a variety of suitable lubricious materials such as Teflon, Paralene, etc. The wire **222** has sufficient tensile strength to allow the sheath **114** to be retracted proximally relative to the core **112**. In some embodiments, the wire **222** may have sufficient column strength to allow the sheath **114** to be advanced distally relative to the core **112** and stents **12**, **14**. For example, if the distal stent **12** has been partially deployed, and the clinician determines that the stent **12** should be re-positioned, the sheath **114** may be advanced distally relative to the stent **12** thereby re-contracting and capturing that stent on the core.

In general, the tensile strength or compressibility of the pull wire **222** may also be varied depending upon the desired mode of action of the outer sheath **114**. For example, as an alternative to the embodiment described above, the outer sheath **114** may be distally advanced by axially distally advancing the pull wire **222**, to release the stent **118** (see FIG. **12**). In a hybrid embodiment, the outer sheath **114** is split into a proximal portion and a distal portion. A pull wire is connected to the proximal portion, to allow proximal retraction to release the proximal stent. A push wire is attached to the distal portion, to allow distal advance, thereby releasing the distal stent. These construction details of the catheter **100** and nature of the wire **222** may be varied to suit the needs of each of these embodiments, as will be apparent to those skilled in the art in view of the disclosure herein.

The stents **118** (see FIG. **12**) are carried on the central support core **112**, and are contracted radially thereon. By virtue of this contraction, the stents **118** (see FIG. **12**) have a cross section which is smaller than that of the conduits **32** and **34** (see FIG. **3**), and they can be introduced into these as will be described below. The stents **118** are preferably disposed on a radially inwardly recessed distal portion **129** of the central core **112** having a smaller diameter than the adjacent portions of the core **112**. See FIG. **12**. This recess **129** is preferably defined distally by a distal abutment such as a shoulder **124** which may be in the form of a proximally facing surface on a distal tip **122**. See FIG. **12**. Distal tip **122** has an outer diameter smaller than that of the stents **118** when the stents are expanded, but greater than the diameter of the stents **118** when they are contracted. See FIG. **12**. This abutment **124** consequently prevents distal advancement of the stents **118** from the core **112** when the stents **118** are contracted. See FIG. **12**.

Proximal movement of the stents **118** (see FIG. **12**) relative to the core **112** is prevented when the stents are in the radially contracted configuration by a proximal abutment surface such as annular shoulder **125**. The distal abutment **124** (see FIG. **12**) and proximal abutment **125** may be in the form of annular end faces formed by the axial ends of annular recess **129** (see FIG. **12**) in the core **112**, for receiving the compressed stents **118**. See FIG. **12**. In one embodiment, illustrated in FIG. **10**A, the proximal abutment **125** is carried by a stent stop **218**. Stent stop **218** may be integral with or attached to the central core **112** (see FIG. **10**), and has an outside diameter such that it is in sliding contact with the inside surface of outer sheath **114** (see FIG. **10**). The compressed stent **14** will thus not fit between the stop **218** and the outer sheath **114** (see FIG. **10**).

The deployment device **100** typically has a soft tapered tip **122** secured to the distal end of inner core **112** (see FIG. **10**), and usually has a guidewire exit port **126** as is known in the art. The tapered distal tip **122** facilitates insertion and atraumatic navigation of the vasculature for positioning the stent system **118** (see FIG. **12**) in the area of the bifurcation to be treated. The distal tip **122** can be made from any of a variety of polymeric materials well known in the medical device arts, such as polyethylene, nylon, PTFE, and PEBAX. In the embodiment shown in FIG. **10**, the distal tip **122** comprises an annular recess **230** sized and adapted to allow a distal portion of the outer sheath **114** (see FIG. **10**) to reside therein such that the transition between the tip and the outer sheath comprises a smooth exterior surface.

The distal tip **122** tapers in one embodiment from an outside diameter which is substantially the same as the outer diameter of the outer sheath **114** (see FIG. **10**) at the proximal end **128** of the tip **122** to an outside diameter at its distal end **130** of slightly larger than the outside diameter of a guidewire. The overall length of the distal tip **122** in one embodiment of the delivery catheter **100** is about 3 mm to about 12 mm, and in one embodiment the distal tip is about 8 mm long. The length and rate of taper of the distal tip **122** can be varied depending upon the desired trackability and flexibility characteristics. The tip **122** may taper in a linear, curved or any other manner known to be suitable.

With reference to FIGS. **11**B and **12**, a distal portion of the central core **112** preferably has a longitudinal axial lumen **132** permitting slideable engagement of the core **112** on a guidewire **170**. The guidewire lumen **132** preferably includes a proximal access port **172** and a distal access port **126** through which the guidewire may extend. The proximal access port **172** may be located at a point along the length of the catheter **100**, as shown in FIGS. **11**A and **11**B, and discussed below (rapid exchange), or the proximal access port **172** may be located at the proximal end **102** of the catheter **100** (over the wire) (see FIG. **9**B). In a rapid exchange embodiment, the proximal access port **172** is generally within about 25 cm of the distal access port **126**, and preferably is between about 20 cm and about 30 cm of the distal access port **126**. The guidewire lumen **132** may be non-concentric with the catheter centerline for a substantial portion of the length of the guidewire lumen **132**.

FIGS. **11**A and **11**B illustrate a transition between a proximal shaft tube **111** and a distal shaft tube **113** including a proximal guidewire access port **172** and a guidewire lumen **132** (see FIG. **11**B). The guidewire lumen **132** (see FIG. **11**B) may extend through a coextrusion, or may be a separate section of tubing which may be bonded, bound by a shrink wrap tubing, or otherwise held relative to the proximal shaft tube **111**.

In the construction shown in cross-section in FIG. **11**B, a proximal shaft tube **111** having a pull wire lumen **220** is joined to a distal shaft tube **113** having a continuation of pull wire lumen **220** as well as a guidewire lumen **132**. In the illustrated embodiment, the proximal shaft tube **111** extends distally into the proximal end of connector tubing **230**. A mandrel is positioned within each lumen, and shrink tubing **236** is heated to bond the joint. An opening is subsequently formed in the shrink wrap to produce proximal access port **172** which provides access to the guidewire lumen **132**.

In one embodiment, the proximal shaft tube **111** comprises a stainless steel hypodermic needle tubing having an outside diameter of about 0.025" and a wall thickness of about 0.003". The distal end **123** of the hypotube is cut or ground into a tapered configuration. The axial length of the tapered zone may be varied widely, depending upon the desired flexibility characteristics of the catheter **100** (see FIG. **9**B). In general, the axial length of the taper is within the range of from about 1 cm to about 5 cm, and, in one embodiment, is about 2.5 cm. Tapering the distal end of the hypotube at the transition with the distal portion of the catheter provides a smooth transition of the flexibility characteristics along the length of the catheter, from a relatively less flexible proximal section to a relatively more flexible distal section as will be understood by those of skill in the art.

Referring to FIG. **12**, the distal end of a dual stent deployment catheter is illustrated, which is also provided with an optional balloon. A guidewire **170** is illustrated as positioned within the guidewire lumen **132**. As can be appreciated by those of skill in the art, the diameter of the guidewire **170** is illustrated as slightly smaller (e.g., by about 0.001-0.003 inches) than the inside diameter of the guidewire lumen **132**. Avoiding a tight fit between the guidewire **170** and inside diameter of guidewire lumen **132** enhances the slideability of the catheter over the guidewire **170**. In ultra small diameter catheter designs, it may be desirable to coat the outside surface of the guidewire **170** and/or the inside walls of the guidewire lumen **132** with a lubricous coating to minimize friction as the catheter **100** is axially moved with respect to the guidewire **170**. A variety of coatings may be utilized, such as Paralene, Teflon, silicone, polyimide-polytetrafluoroethylene composite materials or others known in the art and suitable depending upon the material of the guidewire **170** or central core **112**.

As shown in FIG. **12**, an inflation lumen **134** may also extend throughout the length of the catheter **100** to place a proximal inflation port in fluid communication with one or more inflatable balloons **116** carried by the distal end of the catheter.

The inflatable balloon **116**, if present, may be positioned beneath one or both stents, such as stent **14** as illustrated in FIG. **12** or proximally or distally of the stent, depending upon the desired clinical protocol. In one embodiment, as illustrated in FIG. **12**, the stent may be a self expandable stent which is initially released by proximal retraction by the outer sheath **114** as has been discussed. The balloon **16** is thereafter positioned in concentrically within the stent, such that it may be inflated without repositioning the catheter to enlarge and/or shape the stent. Post stent deployment dilatation may be desirable either to properly size and or shape the stent, or to compress material trapped behind the stent to increase the luminal diameter (e.g., angioplasty). In an alternate mode of practicing the invention, angioplasty is accomplished prior to deployment of the stent either by a balloon on the stent deployment catheter **100** or by a separate angioplasty balloon catheter (or rotational artherectomy, laser or other recanalization device). The stent deployment catheter **100** is thereafter positioned within the dilated lesion, and the stent is thereafter deployed. Thus, balloon dilatation can be accomplished using either the deployment catheter **100** or separate procedural catheter, and may be accomplished either prior to, simultaneously with, or following deployment of one or more stents at the treatment site.

As seen in FIGS. **9** and **9**B, the catheter also includes a handpiece **140** at the proximal end of the catheter **100**. The handpiece **140** is adapted to be engaged by the clinician to navigate and deploy the stent system **118** (see FIG. **12**) as will be described below. The handpiece **140** preferably includes a control **150** adapted to control and indicate a degree of deployment of one or both stents. The control **150** is typically in mechanical communication with the sheath **114** such that proximal retraction of the control **150** results in proximal retraction of the sheath **114**. Those skilled in the art will recognize that distal motion, rotational movement of a rotatable wheel, or other motion of various controls **150** may alternatively be employed to axially move such as distally advance or proximally retract the sheath **114** to expose the stent or stents.

The illustrated control **150** is preferably moveable from a first position to a second position for partial deployment of the first stent **12**, and a third position for complete deployment of the first stent **12**. A fourth and a fifth positions may also be provided to accomplish partial and complete deployment of an optional second stent **14**. The control **150** may include indicia **160** adapted to indicate the amount of each stent **12** or **14** which has been exposed as the sheath **114** is retracted relative to the core **112**. The indicia **160** may include dents, notches, or other markings to visually indicate the deployment progress. The control **150** may also or alternatively provide audible and/or tactile feedback using any of a variety of notches or other temporary catches to cause the slider to "click" into positions corresponding to partial and full deployment of the stents **12**, **14**. Alignable points of electrical contact may also be used. Those skilled in the art will recognize that many methods and structures are available for providing a control **150** as desired.

The catheter **100** may include a plurality of radiopaque markers **250** (seen best in FIGS. **2**, **10**, and **10**A) impressed on or otherwise bonded to it, containing a radiopaque compound as will be recognized by those skilled in the art. Suitable markers can be produced from a variety of materials, including platinum, gold, barium compounds, and tungsten/rhenium alloy. Some of the markers **250**A (see FIG. **2**) may have an annular shape and may extend around the entire periphery of the sheath **114**. The annular markers **250**A (see FIG. **2**) may be situated, in the area of the distal end of the first stent **12**, the distal end of the second stent **14**, and in the area of the bridge **18** (FIG. **1**) or space separating the stents **12**, **14**. A fourth marker **252** may be situated at substantially the halfway point of the generatrix of the lower segment of the second stent **14** situated in the continuation of the bridge **18** and of the diametrically opposite generatrix. FIG. **2** shows a marker **252** with a diamond shape and a small thickness provided along the outer sheath **114** at a desirable position for determining the rotational position of the catheter within the bifurcation. The markers **250** and **252** (see FIG. **2**) may be impressed on the core **112**, on the sheath **114**, or directly on the stents **12**, **14** such as on the bridge **18**, and not on the sheath **114**.

With reference to FIGS. **10** and **10**A, three markers **253** are shown disposed at a distal end of the second stent **14** and spaced at 120° relative to one another. Three markers **254** are also disposed at a proximal end of the first stent **12**, and spaced at 120° relative to one another. Each stent **12**, **14** also includes a single marker **210** at its opposite end (e.g., the first stent **12** has a single marker **210** at its distal end, and the second stent **14** has a single marker **210** at its proximal end). Of course, other marker arrangements may be used as desired by the skilled artisan.

A central marker **252** makes it possible to visualize, with the aid of a suitable radiography apparatus, the position of a bridge **18** separating the two stents **12**, **14**. Thus allowing a specialist to visualize the location of the second stent **14** so that it can be correctly positioned in relation to the widened zone **46** and carina. The end markers **250**A (see FIG. **2**) allow a specialist to ensure that the stents **12**, **14** are correctly positioned, respectively, in the main/principal conduit **32** (see FIG. **3**) and the secondary/branch conduit **34** (see FIG. **3**).

A diamond-shaped marker **252** as shown in FIG. **2** is, for its part, visible in a plan view or an edge view, depending on whether it is oriented perpendicular or parallel to the radius of the radiography apparatus. It thus makes it possible to identify the angular orientation of the stents **12**, **14** in relation to the bifurcation **30**, so that the part of the second stent **14** having the greatest expansion can be placed in an appropriate manner in relation to the widened transition zone **46**.

Methods of positioning and deploying a pair of dissimilar stents in an area of a bifurcation will now be discussed with reference to FIGS. **3-6** and **13-17**. Although portions of the following discussion refer to delivery of two dissimilar stent portions, those skilled in the art will recognize that a larger or smaller number of stents, and/or stents having similar expanded configurations may also be used while realizing certain aspects of the present invention.

A method of delivering a stent system as described above generally and illustrated in FIGS. **13-17** includes locating the bifurcation **30** to be treated, providing a suitable delivery catheter **100**, positioning the distal portion **107** (see FIG. **9**) of a delivery catheter with stents **12**, **14** (see FIG. **16**) disposed thereon in the branch of the bifurcation to be treated, partially deploying the first stent **12** in a branch vessel **34**, observing and adjusting the position of the first stent **12** if necessary, then fully deploying the first stent **12**. See FIG. **14**. The second stent **14** is partially deployed (see FIG. **16**), and preferably the position is again observed such as by infusing contrast media through the pull wire lumen **220** (see FIG. **11**B) under fluoroscopic visualization. The position of the second stent **14** (see FIG. **16**) may be adjusted if necessary, and finally the second stent **14** is fully deployed (see FIG. **17**). Methods of navigating catheters through blood vessels or other fluid conduits within the human body are well known to those skilled in the art, and will therefore not be discussed herein.

The delivery catheter **100** may be constructed according to any of the embodiments described above such that the stents **12**, **14** may be selectively deployed (see FIG. **17**) by axially displacing the outer sheath **114** along the delivery catheter, thereby selectively exposing the stent system **10**. This may be accomplished by holding the sheath **114** fixed relative to the bifurcation, and selectively distally advancing the central core **112**. Thus, the present invention contemplates deploying one or more stents by distally advancing the central core (inner sheath) rather than proximally retracting the outer sheath as a mode of stent deployment. The stent system may alternatively be deployed by holding the central core fixed relative to the bifurcation and selectively proximally retracting the sheath **114**. The catheter may also be adapted to allow the sheath to be advanced distally, thereby re-contracting the partially deployed stents on the central core **112** to allow repositioning or removal.

In order to visualize the position of a partially-deployed stent with a suitable radiographic apparatus, a contrast media may be introduced through the catheter to the region of the stent placement. Many suitable contrast media are known to those skilled in the art. The contrast media may be introduced at any stage of the deployment of the stent system **10**. For example, a contrast media may be introduced after partially deploying the first stent **12**, after fully deploying the first stent **12** (see FIG. **15**), after partially deploying the second stent **14** (see FIG. **16**), or after fully deploying the second stent **14** (see FIG. **17**).

The degree of deployment of the stent system **10** is preferably made apparent by the indicators on the handpiece **140** (see FIG. **9**) as described above. The handpiece **140** (see FIG. **9**) and outer sheath are preferably adapted such that a motion of a control on the handpiece **140** (see FIG. **9**) results in proximal motion of the outer sheath **114** relative to the distal tip **122** and the stents **12**, **14** (see FIG. **17**). The handpiece **140** (see FIG. **9**) and sheath **114** may also be adapted such that the sheath may be advanced distally relative to the stents **12**, **14** (see FIG. **17**), thus possibly re-contracting one of the stents **12**, **14** (see FIG. **17**) on the core **112**. This may be accomplished by providing a pull wire **222** having a distal end **223** (see FIG. **9**E) attached to a portion of the outer sheath **114**, and a proximal end adapted to be attached to the handpiece **140** (see FIG. **9**). Alternatively, the handpiece **140** (see FIG. **9**) may be omitted, and the retraction wire **222** may be directly operated by the clinician.

In an alternative embodiment, indicated by FIGS. **4**-**6**, the first and/or second stent **12**, **14** (see FIG. **6**) may be deployed in a single motion, thus omitting the step of re-positioning the stent **12**, **14** (see FIG. **6**) before fully deploying it. The sheath **114** is then progressively withdrawn, as is shown in FIGS. **5** and **6**, in order to permit the complete expansion of the stents **12**, **14**.

In a preferred embodiment, the second stent **14** (see FIG. **6**) is placed in close proximity to the first stent **12** (see FIG. **6**). For example, the distal end **38** (see FIG. **6**) of the second stent **14** (see FIG. **6**) may be placed within a distance of about 4 mm of the proximal end **42** (see FIG. **6**) of the first stent **12** (see FIG. **6**), more preferably this distance is less than about 2 mm, and most preferably the first and second stents **12**, **14** (see FIG. **6**) are placed within 1 mm of one another. Those skilled in the art will recognize that the relative positioning of the first and second stents **12**, **14** (see FIG. **6**) will at least partially depend on the presence or absence of a bridge **18** (see FIG. **6**) as discussed above. The axial flexibility of any bridge **18** (see FIG. **6**) will also affect the degree of mobility of one of the stents relative to the other. Thus, a stent system **10** (see FIG. **5**) will preferably be chosen to best suit the particular bifurcation to be treated.

As mentioned above, the stents **12**, **14** (see FIG. **6**) may be self-expanding or balloon-expandable (e.g., made of a substantially non-elastic material). Thus the steps of partially deploying the first and/or the second stent may include introducing an inflation fluid into a balloon on which a stent is disposed, or alternatively the stent may be allowed to self-expand. In the case of a balloon-expandable second stent **14** (see FIG. **6**), the balloon **116** (FIG. **12**) on which the second stent **14** (see FIG. **6**) is disposed may be specifically adapted to correspond to the particular shape of the second stent **14** (see FIG. **6**). Specifically, such a balloon will preferably have a larger diameter at a distal end than at a proximal end.

After complete expansion of the stents **12**, **14** (see FIG. **6**), the distal end of the delivery catheter **100** including the core **112** and the guidewire **170** may be withdrawn from the conduits and the vasculature of the patient. Alternatively, additional stents may also be provided on a delivery catheter, which may also be positioned and deployed in one or both branches of the bifurcation. For example, after deploying the second stent **14** as shown in FIG. **6** or **17**, the catheter **100** and guidewire **170** may be retracted and re-positioned in the second branch vessel such that a third stent may be positioned and deployed therein.

Referring to FIG. **18**, a second branch stent **13** may be deployed in the second branch, such that both branch vessels in the bifurcation are fully stented. The second branch stent **13** may be either a self expandable or balloon expandable stent such as those well known in the art and disclosed in part elsewhere herein. The second branch stent **13** may be deployed before or after the main stent **14** and/or first branch stent **12**. In one application of the invention, the main vessel stent **14** and first branch stent **12** are positioned as has been described herein. A stent deployment catheter (not illustrated) such as a balloon catheter or self expanding stent deployment catheter is transluminally advanced to the bifurcation, and advanced through the main vessel stent **14**. The second branch vessel stent **13** may then be aligned in the second branch vessel, such that it abuts end to end, is spaced apart from, or overlaps with the distal end of the main branch stent **14**. The second branch vessel stent **13** may then be deployed, and the deployment catheter removed.

As will be clear to those skilled in the art, the stent system **10** and stent delivery system **100** described herein is useful in treating a number of pathological conditions commonly found in vascular systems and other fluid conduit systems of human patients. Treatment with the apparatus can include re-establishing the appropriate diameter of a bifurcation in cases of arteriosclerosis or internal cell proliferation, or in rectifying a localized or nonlocalized dissection in the wall of the conduit, or in re-creating a bifurcation of normal diameter while eliminating the aneurysmal pouch in cases of aneurysm.

One or more of the stents deployed in accordance with the present invention may be coated with or otherwise carry a drug to be eluted over time at the bifurcation site. Any of a variety of therapeutically useful agents may be used, including but not limited to, for example, agents for inhibiting restenosis, inhibiting platelet aggregation, or encouraging endothelialization. Some of the suitable agents may include smooth muscle cell proliferation inhibitors such as rapamycin, angiopeptin, and monoclonal antibodies capable of blocking smooth muscle cell proliferation; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, acetyl salicylic acid, and mesalamine, lipoxygenase inhibitors; calcium entry blockers such as verapamil, diltiazem and nifedipine; antineoplastic/antiproliferative/anti-mitotic agents such as paclitaxel, 5-fluorouracil, methotrexate, doxorubicin, daunorubicin, cyclosporine, cisplatin, vinblastine, vincristine, colchicine, epothilones, endostatin, angiostatin, Squalamine, and thymidine kinase inhibitors; L-arginine; antimicrobials such astriclosan, cephalosporins, aminoglycosides, and nitorfurantoin; anesthetic agents such as lidocaine, bupivacaine, and ropivacaine; nitric oxide (NO) donors such as lisidomine, molsidomine, NO-protein adducts, NO-polysaccharide adducts, polymeric or oligomeric NO adducts or chemical complexes; anti-coagulants such as D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, enoxaparin, hirudin, Warafin sodium, Dicumarol, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet factors; interleukins, interferons, and free radical scavengers; vascular cell growth promoters such as growth factors, growth factor receptor antagonists, transcriptional activators, and translational promotors; vascular cell growth inhibitors such as growth factor inhibitors (e.g., PDGF inhibitor—Trapidil), growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin; Tyrosine kinase inhibitors, chymase inhibitors, e.g., Tranilast, ACE inhibitors, e.g., Enalapril, MMP inhibitors, (e.g., Ilomastat, Metastat), GP IIb/IIIa inhibitors (e.g., Intergrilin, abciximab), seratonin antagnonist, and 5-HT uptake inhibitors; cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogeneus vascoactive mechanisms. Polynucleotide sequences may also function as anti-restenosis agents, such as p15, p16, p18, p19, p21, p27, p53, p57, Rb, nFkB and E2F decoys, thymidine kinase ("TK") and combinations thereof and other agents useful for interfering with cell proliferation. The selection of an active agent can be made taking into account the desired clinical result and the nature of a particular patient's condition and contraindications. With or without the inclusion of a drug, any of the stents disclosed herein can be made from a bioabsorbable material.

The bifurcation **30** shown in FIG. **3** has excrescences **35** which create a narrowing in cross section, which impedes the flow of the liquid circulating in the conduits **32** and **34**. In the case of a vascular bifurcation, these excrescences are due, for example, to arteriosclerosis or cellular growth. The stent system described herein permits treatment of this bifurcation by re-establishing the appropriate diameter of the conduits **32**, **34** and of the widened transition zone **46**.

As shown in FIG. **7**, the stent system **10** can also be used to treat an aneurysm **242**. An aneurysm **242** is defined as a localized, pathological, blood-filled dilatation of a blood vessel caused by a disease or weakening of the vessel's wall. Thus it is desirable to provide a "substitute" vessel wall in an area of an aneurysm. For this purpose, the first or second stent **12**, **14** may be at least partially covered by a film **240** which is substantially impermeable to the fluid circulating in the conduits **32**, **34**. Many suitable films are known to those skilled in the art such as polyester, polytetrafluoroethylene (PTFE), high and medium density polyethylenes, etc. The film may be sewn onto the stents **12**, **14**, or it may be folded around a stent such that as the stent is expanded within the vessel **32**, the film **240** is trapped and held between the stent and the vessel wall. The stent then guides the liquid through the bifurcation **30** and consequently prevents stressing of the wall forming the aneurysm **242**.

In some embodiments, each of the first (cylindrical) stent **12** and second (tapered) stent **14** can be provided on its own individual delivery catheter. With reference to FIGS. **19-22**, embodiments of stent delivery systems for use in deploying a single stent for treatment of a pathology at a bifurcation are described below.

FIGS. **19** and **20** illustrate a system configured to deploy a single stent having a substantially straight or cylindrical shape when in its expanded condition, for example, the stent **12** could be substantially the same as the cylindrical stent **12** of the above embodiments. The system generally includes an elongate delivery catheter **100** substantially as described above and having a single stent **12** disposed on the distal end of the catheter. The stent **12** is surrounded by a retractable sheath **114** having a plurality of radial restraints such as retaining bands **121**. In the illustrated embodiment, five retaining bands **121** are provided to retain the stent **12** in a compressed condition. Alternatively, other numbers of retention bands **121** may also be used. For example, one, two, three, four, or six or more retention bands **121** may be used as desired for a particular stent.

FIG. **20** shows the system of FIG. **19** with a proximal detail of the outer sheath **114**. The delivery system for use with the straight stent **12** typically includes a stent stop **218** with an annular shoulder **125** which the proximal end of the stent **12** will abut as the sheath **114** is retracted. As shown in FIG. **20**, the stent stop **218** will abut the proximal markers **254** (in an embodiment having such markers) as the sheath is retracted by a proximal force on the pull wire **222** which is attached to the sheath **114** at a retraction band **226**.

FIGS. **21** and **22** illustrate a system configured to deploy a single stent having a substantially conical or otherwise tapered shape when in its expanded condition. For example, the conical stent **14** may be the same or similar to the main branch stent **14** described above. The system of FIG. **21** generally includes an elongate delivery catheter **100** substantially as described above and having a single conical stent **14** disposed on the distal end of the catheter **100**. The stent **14** is surrounded by a retractable sheath **114**, which can include a radial retention structure such as a plurality of retaining bands **121**. In the illustrated embodiment, four retaining bands **121** are provided to retain the stent **14** in a compressed condition and resist imprinting into the sheath **114**. This number of retaining bands is particularly suited to the conical stent **14** according to the embodiment illustrated in FIG. **23**A. Alternatively, other numbers of retention bands **121** may also be used. For example, one, two, three, five, or six or more retention bands **121** may be used as desired for a particular conical stent.

FIG. **22** shows the system of FIG. **21** with a proximal detail of the outer sheath **114**. The delivery system for use with the conical stent **14** can include a stent stop **218** with an annular shoulder **125** disposed within the outer sheath configured to provide an edge against which the stent **14** may abut as the sheath is retracted. The stent stop **218** of the present embodiment illustrated in FIGS. **21** and **22**, comprises a slot **211** in which the proximal marker **210** of the conical stent **14** may rest. By contrast, this slot **211** may be omitted in the embodiment illustrated in FIGS. **19** and **20** configured for use with a cylindrical stent, or if unnecessary in view of the particular conical stent design.

A delivery system adapted for use with a single stent will often be sized differently from the two-stent delivery system described above as will be apparent to those of skill in the art in view of the disclosure herein. For example, the axial length of the stent receiving recess **129** (see FIG. **12**) in a single stent delivery catheter will often be somewhat shorter than a dual-stent catheter. In general, the axial length of the stent receiving recess **129** (see FIG. **12**) in a single, tapered stent system for use in a bifurcation of the coronary artery will be within the range of from about 8 mm to about 18 mm, and often within the range of from about 10 mm to about 13 mm. The tapered stent for use in coronary applications is generally at least 10 mm in axial length, for example, 10 mm, 11 mm, 12 mm, and 13 mm can be used. For coronary applications, the proximal unconstrained expanded diameter is typically in the range of from about 3 mm to about 6 mm, and often from about 3.5 mm to about 5.5 mm, and in one embodiment the proximal expanded diameter is about 4.5 mm. The distal unconstrained expanded diameter is typically in the range of from about 5 mm to about 8 mm, and often from about 5.5 mm to about 7.5 mm. In one embodiment of a tapered stent for use in coronary applications, the distal expanded diameter is about 6.5 mm. In one embodiment, the outer sheath **114** and the inner stent receiving recess of a single stent catheter can be about 11 mm shorter than the corresponding parts in a two-stent system.

A tapered stent for use in carotid or biliary applications generally has an axial length in the range of about 15 mm up to about 20 mm, and often between about 17 mm and about 19 mm. In one particular embodiment a tapered stent for use in carotid or biliary applications has an axial length of about 18 mm. For carotid or biliary applications, the proximal expanded diameter is typically in the range of from about 8 mm to about 12 mm, and often from about 9 mm to about 11 mm, and in one embodiment the proximal expanded diameter is about 10 mm. The distal expanded diameter is typically in the range of from about 11 mm to about 15 mm, and often from about 12 mm to about 14 mm. In one embodiment of a tapered stent for use in coronary applications, the distal expanded diameter is about 13 mm. In general, the distal expanded diameter is generally at least about 40% of the axial length, and often the distal expanded diameter is more than 50% of the axial length.

FIGS. **23**A and **23**B illustrate a bifurcation stent **300** in accordance with another embodiment of the present invention. The bifurcation stent **300** has a first end **302** (see FIG. **23**A) (which is sometimes referred to as the proximal end **302**) and a second end **304** (which is sometimes referred to as the distal end **304**). The bifurcation stent **300** is generally formed from a series of segments **306** that are connected to one another by links **312**. Each segment **306** is formed from struts **308** that generally extend in a zigzag pattern, although the struts **308** can be provided in any of a number of curved, sinusoidal or other shapes and patterns. In one embodiment, the struts **308** extend substantially linearly from a proximal apex to a distal apex.

The proximal end **302** (see FIG. **23**A) of the bifurcation stent **300** includes a proximal marker support **328** for holding a proximal marker **330**. The proximal end **302** (see FIG. **23**A) can include more than one proximal marker support **328**, such as two or three proximal marker supports **328**, five proximal marker supports **328**, seven proximal marker supports **328**, or more. The proximal end **302** (see FIG. **23**A) of the bifurcation stent **300** generally includes at least one proximal marker support **328**, and often includes an odd number of proximal marker supports **328**.

The distal end **304** (see FIG. **23**A) of the bifurcation stent **300** includes at least one distal marker support **324** for holding at least one distal marker **326**. More than one distal marker support **324** can be provided at the distal end **304** (see FIG. **23**A). For example, three distal marker supports **324** can be provided as is illustrated in FIG. **23**A. In other embodiments more than three distal marker supports **324** are provided at the distal end **304** (see FIG. **23**A) of the bifurcation stent **300**, such as five distal marker supports **324**, seven distal marker supports **324**, or more.

In the illustrated embodiment, the marker support **324** is in the form of an annular band **325** (see FIG. **23**D) of material, defining an opening **327** (see FIG. **23**D) there through for receiving marker **326**. The marker support **324** may be formed separately from the stent and bonded thereto, using any of a variety of techniques known in the art such as brazing, soldering, welding and the like. Preferably, however, the marker support **324** is integrally formed with the stent such as by cutting from tube stock using laser cutting or other etching procedure in the same process as the formation of the wall pattern of the stent. This avoids the need to have a bonded joint.

Referring to FIG. **23**D, the annular band **325** defines an opening **327** for receiving the marker **326**. The annular band **325** and opening **327** may have any of a variety of shapes, such as round, square, rectangular, oval, or other. In the illustrated embodiment, the opening **327** has an elongated or oval configuration having a major axis extending in a circumferential direction and a minor access extending in an axial direction. The circumferential dimension of the opening **327** is greater than the axial dimension of the opening **327** in the illustrated embodiment, which allows maximization of the mass of the marker while minimizing the axial length thereof. The circumferential dimension of the opening **327** may be anywhere within the range of from about 0.5 mm to about 1.0 mm and, in one embodiment, is about 0.7 mm. The axial dimension of the opening **327** may be anywhere within the range of from about 0.3 mm to about 0.8 mm, and, in one embodiment, is about 0.5 mm. The width of the annular band **325** taken in plan view as illustrated in FIG. **23**D may be anywhere within the range of from about 0.08 mm to about 0.250 mm. In one embodiment, the width is about 0.12 mm. The width of the adjacent strut **329** taken from the same perspective may be anywhere within the range of from about 0.075 mm to about 0.250 mm. In general, the width of the annular band **325** is slightly greater than the width of the adjacent strut **329**. In one embodiment, the width of the adjacent strut **329** is about 0.1 mm.

Referring to FIG. **23**E, there is illustrated a side elevational view of a marker **326** prior to attachment to a stent. The marker **326** generally comprises a body portion **331** having a first cross sectional area and a head **333** having a second, greater cross sectional area, to form a generally mushroom shaped component. The body **331** has a leading end **335** on the opposite end of the body from the head **333**. The body **331** may have a generally cylindrical configuration, or may have a non-round cross sectional configuration such as oval, elliptical square or other. The body **331** is generally contemplated to have a diameter within the range of from about 0.3 mm to about 0.75 mm and, in one embodiment, about 0.5 mm. The axial length of the component from the leading end **335** through the head **333** may be anywhere within the range of from about 0.25 mm to about 0.5 mm and, in one embodiment, is about 0.38 mm. The diameter of the head **333** is preferably greater than the diameter of the body **331** by at least about 0.1 mm and, preferably, at least about 0.15 mm. In one embodiment, the diameter of the head **333** is within the range of from about 0.5 mm to about 0.9 mm, and, in one embodiment, is about 0.7 mm. The axial length of the head **333** is preferably at least about 0.05 mm and no greater than about 0.2 mm. In one embodiment, the length is about 0.08 mm. Dimensions outside of the recited ranges may also be used, depending upon stent dimensions and design.

In assembly, the marker **326** is positioned within the lumen of the stent and leading end **335** is advanced through the opening **327** of the annular band **325** from the inside ("lumenal side") of the stent to the outside (ablumenal side) of the stent. This positions the integrally pre formed head **333** against the inside surface of the stent. The body **331** is thereafter axially compressed such as by impact or other compression against the surface **335**, to reconfigure the surface **335** into a corresponding mushroom shape, thereby increasing its radial diameter relative to the diameter of the body **331**, and provides a locking surface on the outside surface of the stent. A marker starting with an axial length of approximately 0.38 mm will be reduced in axial length to somewhere within the range of from about 0.2 mm to about 0.3 mm following compression. In one embodiment, the axial length of the marker post compression is approximately 0.24 mm, when mounted in a stent having a wall thickness of about 0.160 mm. Compression may it be accomplished by positioning the head **333** against an anvil surface within the stent, and impacting the surface **335** with a compression pin. The surface of the anvil and the compression pin may be planer or may be radiused, to curve the resulting end surfaces of the marker with a radius that corresponds to the radius of the stent.

A mounted marker is illustrated in FIG. **23**F. In one implementation of the invention, the axial length through the marker is about 0.244 mm, in a stent having a wall thickness of about 0.160 mm. In one implementation, the marker **326** comprises gold, having a mass of about 1.70 mg. Gold markers will generally have a mass in excess of at least about 1.0

mg, although the mass of the marker may be varied depending upon the desired degree of visibility during the procedure.

The marker support **324** is positioned "off board" or beyond the end of the stent. In this context, the end of the stent is the plane which extends transversally to the longitudinal axis of the stent, and contains a plurality of apexes or peaks **320**. This orientation positions the radiopaque marker **326** slightly beyond the end of the stent measured in an axial direction. The length or diameter of the marker support **324** measured parallel to the longitudinal axis of the stent is generally at least 10%, in some embodiments at least about 20%, and may be at least about 30% or more of the axial length of the adjacent segment **306**.

The proximal and distal markers **330**, **326** can be any of a variety of markers known to those of skill in the art, and can have any of a variety of shapes. The proximal and distal markers **330**, **326** can include any of the markers described herein. For example, the markers **330**, **326** can be radiopaque or have radiopaque properties. The markers **330**, **326** can be cylindrical (circular in a side view), diamond-shaped, square, frustoconical, or any other shape suitable for use with the bifurcation stent **300**. The markers **330**, **326** can be attached to the bifurcation stent in any of a variety of ways, including crimping, press-fitting, locking, screwing, or twisting them into the proximal and distal marker supports **328**, **324** with or without soldering, brazing, adhesives or other attachment feature. In other embodiments the markers **328**, **324** are painted onto the segments **306**, stents **308**, and/or proximal and distal marker supports **328** of the bifurcation stent **300**.

The struts **308** of each cell segment of the bifurcation stent **300** form distal peaks **320** and proximal peaks **322** as the struts **308** extend around the perimeter of the bifurcation stent **300** in a zigzag pattern. Links **312** connect adjacent segments **306** by extending in a distal direction from the distal peak **320** of one segment **306** to a proximal peak **322** of an adjacent segment **306**.

The links **312** can have any of a variety of cross sectional shapes known to those of skill in the art, such as rectangular, cylindrical, tapered, or any other shape. In one embodiment, the links **312** have a constant transverse area through their length, and in other embodiments the links **312** taper to a smaller cross-sectional area (e.g., diameter) along their length to increase flexibility of the bifurcation stent **300**. For example, in one embodiment, the links **312** or at least some of the links, have an hourglass shape, such that they are wider at the link ends than at the link middle portion. In other embodiments, the links **312** are wider at one end than at the other end. The link **312** can have a cross-sectional area substantially equal to, less than, or greater than the diameter of an adjacent strut **308**. The links **312** may be selected in a variety of lengths. For example, in some embodiments, the links **312** are no more than about 0.5 mm, no more than about 0.75 mm, or less than about 1 mm in length.

The bifurcation stent **300** can be enlarged from a collapsed, or reduced-diameter configuration to an expanded, or enlarged-diameter configuration, such as illustrated in FIG. **23**A. When expanded, the bifurcation stent **300** has a proximal (upstream, as deployed) diameter **316** that is smaller than its distal (downstream, as deployed) diameter **318**. A central lumen **334** extends through the bifurcation stent **300** from its proximal end **302** to distal end **304**. In some embodiments, the stent **300** proximal diameter **316** is no more than about 3.25 mm, no more than about 4.75 mm, or no more than about 5.25 mm and the distal diameter **318** is at least about 5.5 mm, at least about 7 mm, or at least about 8 mm. In some embodiments the stent **300** has a proximal diameter **316** in the range of about 2-4 mm and a distal diameter of about 4-7 mm. In other embodiments, the proximal diameter **316** is in the range of about 3-5 mm and distal diameter **318** is in the range of about 5-9 mm. In other embodiments, the proximal diameter is in the range of about 4-7 mm and the distal diameter **318** is in the range of about 8-14 mm.

The length of each strut **308** from its distal peak **320** to its proximal peak **322** defines a strut length **310**. In addition, the distance between distal and proximal peaks **320**, **322** of adjacent segments **306** defines a link length **314**. Links **312** can be uniform in link length **314**, or non-uniform, as may be clinically desired. For example, varying link length **314** can provide control over the flexibility of the bifurcation stent **300** between each segment **306**. In addition, providing more links **312** between adjacent cells **306** can improve repositionability of the bifurcation stent **300**. For example, when a link **312** connects every pair of adjacent distal and proximal peaks **320**, **322**, the bifurcation stent **300** will not bind up when deployed, and will exit the deployment catheter as an even cone (or flare).

FIG. **23**B shows a rolled out flat view of the bifurcation stent **300** of FIG. **23**A to clearly illustrate one embodiment of a sidewall pattern of a bifurcation stent **300**. Strut length **310** and link length **314** are clearly shown in FIG. **23**B. In some embodiments, the struts **308** all have about the same strut length **310**. In other embodiments, the strut length **310** of the struts **308** of the distal most segment **306** are greater than the strut length **310** of the struts **308** of the other segments. Strut lengths **310** are often in the range of about 1-3 mm. The link lengths **314** are sometimes in the range of 0.5-0.75 mm, or less than about 1 mm.

The stent illustrated in FIGS. **23**A and **23**B has a tapered configuration in the unconstrained expanded configuration, and comprises four segments **306**. Depending upon the desired performance characteristics and dimensions of the stent, anywhere from one segment **306** to 10 or 12 or more segments **306** may be utilized. In the embodiment illustrated in FIG. **23**C, for example, a stent having five segments **306** is illustrated in an expanded configuration.

The bifurcation stent **300** illustrated in FIG. **23**A has a tapered shape in its unconstrained, expanded configuration. However, any of a variety of configurations may be used as a bifurcation stent **300**, generally sharing the characteristic that the distal and **304** has a greater cross sectional area than the proximal end **302** in an unconstrained expansion. For example, a flared bifurcation stent **300** is illustrated in FIGS. **24**A-C. The flared bifurcation stent **300** of FIG. **24**A includes, in one embodiment, many of the same components as the bifurcation stent **300** of FIG. **23**A. However, the flared bifurcation stent **300** can have longer strut length **310** (see FIG. **24**A) segments **306** located at its distal end **304** than at its proximal end **302**.

The taper angle or flare configuration may be selected to accommodate the particular bifurcation into which the bifurcation stent **300** is to be deployed. For example, a bifurcation stent **300** can have a half-angle taper of at least about 20°, at least about 25°, or at least about 30°. In other embodiments the bifurcation stent **300** has a half-angle taper more than 35°.

The bifurcation stent **300** often has a symmetrical taper angle or flare configuration such that the unconstrained, expanded taper angle or flare configuration is uniform about its outer surface. Such configurations may be advantageous when deploying the bifurcation stent **300** into a substantially cylindrical bifurcation having a near circular cross section. However, in other embodiments, where the cross section of the bifurcation is non-cylindrical (e.g., oval, elliptical, elongated, etc.), the bifurcation stent **300** can have a corresponding asymmetrical taper angle or flare configuration. When asymmetrical, the taper angle or flare configuration as viewed from one side view of the bifurcation stent **300** is different than the taper angle or flare configuration as viewed from a different side view of the bifurcation stent **300**. In either case, the stent can be configured to adopt the configuration of the native anatomy upon deployment.

Additional links **312** may be provided between adjacent segments **306** of the bifurcation stent **300**. For example, in the bifurcation stent of FIG. **23**A, as best seen in FIG. **23**B, the tapered bifurcation stent **300** has seven links **312** connecting the most proximal segment **306** and the segment **306** adjacent to it. The distal-most segment **306** is connected to the segment **306** adjacent to it with four links **312**. However, in the flared bifurcation stent **300** of FIGS. **24**A-C, the most proximal segment **306** is connected to its adjacent segment with seven links **312**, and the distal-most segment **306** is connected to its adjacent segment **306** with seven links **312** as well.

In the illustrated embodiment, each segment **306** has approximately 14 proximal apexes **322** and 14 distal apexes **320**. Depending upon the desired stent performance and intended anatomy, the number of apexes may be varied considerably. Anywhere from approximately 6 apexes to 20 apexes or more may be used, depending upon desired performance. In the embodiment illustrated in FIG. **23**A, the proximal segment **306** has 14 distal apexes **320** and 7 links **312**. The links **312** are spaced apart evenly around the circumference of the stent, such that every other apex is provided with a link **312**. Alternatively, links **312** may be provided on every third apex, every fourth apex, or more. Typically, no fewer than two or three links **312** will be positioned between two adjacent segments **306**. In higher link density configurations, links **312** may be provided on every two out of three adjacent apexes, three out of four, or four out of five or more, including providing a link **312** on every apex around the circumference of a segment **306**. As the ratio of links **312** to apexes increases, certain functional characteristics of the stent may be improved, however at the cost of reduced stent flexibility as will be understood by those skilled in the art.

When expanded, such as illustrated in FIGS. **23**A and **24**A, the bifurcation stent **300** has an expanded length **332** extending from its proximal end **302** to its distal end **304**. When compressed, the bifurcation stent **300** has a compressed length **336** extending from its proximal end **302** and distal end **304** as well. In some embodiments, the expanded length **332** and compressed length **336** are equal or substantially the same. In such cases, the bifurcation stent **300** is non-foreshortening or substantially non-foreshortening. In other embodiments, the expanded length **332** of the bifurcation stent **300** is less than the compressed length **336**. The difference between the compressed length **336** and the expanded length **332** can be no more than about 1%, no more than about 1.5%, no more than about 5%, or less than about 7%.

The bifurcation stent **300** is often self-expanding, although it can be balloon inflatable when desired. A self-expandable bifurcation stent **300** can be made from pseudoelastic alloys, such as nickel titanium, or NITINOL®, or Elgiloy, any other pseudoelastic alloy known to those of skill in the art. In addition, the bifurcation stent can be made from stainless steel, polymers, or plastics.

In some embodiments, the bifurcation stent **300** is cut from tube, such as by laser cutting techniques known in the art. However, the bifurcation stent **300** can alternatively be formed by cutting the desired pattern into a sheet of material and wrapping the sheet into a cylindrical, frustoconical, or flared form. In other embodiments, the bifurcation stent is formed by weaving wire into the desired shape.

FIG. **25** illustrates a vascular bifurcation **400** into which a bifurcation stent in accordance with any embodiments disclosed herein may be delivered. The vascular bifurcation **400** typically occurs at the branching of a main vessel **402** into a first branch vessel **404** and a second branch vessel **406**. Fluid generally flows through the vasculature from the main vessel **402** into each of the first and second branch vessels **404**, **406**. The direction of fluid flow **408** is generally in a downstream orientation from a proximal location **410** with respect to the bifurcation **400** to distal locations **412** with respect to the bifurcation **400**.

The carina **414** is formed at the point where the first branch vessel **404** and second branch vessel **406** meet. The carina **414** generally has a saddle-like shape, and in many cases can provide smooth blood flow from the main vessel **402** into each of the branch vessels **404**, **406**.

A reference diameter **416** is sometimes determined as the inside diameter of the main vessel **402** at a location proximal of the first and second branch vessels **404**, **406** and carina **414**. For example, the reference diameter **416** can be the diameter of the main vessel **410** at a location about 2-4 mm, about 4-6 mm, about 5-7 mm, or about 5 mm proximal of the carina **414**.

In some cases, a lesion (not shown) is formed along the inside wall of the main vessel **402** proximal to the bifurcation **400**. In such cases, the reference diameter **416** is generally the inside diameter of the main vessel **402** at a location proximal to the lesion. For example, the reference diameter **416** can be the diameter of the main vessel **410** at a location about 2-4 mm, about 4-6 mm, about 5-7 mm, or about 5 mm proximal of the lesion. In other embodiments, the reference diameter **416** is the diameter of the main vessel **402** just proximal or upstream from the widening transitional zone. In situations where there is a lesion at the bifurcation, the reference diameter **416** can be the diameter of the main vessel **402** just proximal or upstream from the lesion.

A carinal plane **418** extends in a direction transverse to the main vessel **402** intersecting the main vessel **402** as it branches into both the first and second branch vessels **404**, **406** tangential to the carina **414**. The ostium diameter **420** is generally the diameter of the main vessel **402** at the carinal plane **418**, across both branch vessels.

In some embodiments, it may be advantageous or clinically indicated to dilate the stenosed aspect of bifurcation **400** before deploying the bifurcation stent **300**. For example, a balloon catheter (not shown) can be delivered to the bifurcation **400** and deployed such that when inflated, the wall of the balloon contacts and applies outward force to the vessel wall to either branch or the main vessel at the bifurcation **400**. This pre-dilation may be performed using any of a variety of techniques, including using two guide wires and sequential and/or kissing inflations or balloons.

FIG. **26** illustrates the deployment of a bifurcation stent at a bifurcation in accordance with one embodiment of the present invention. A second guidewire, which may be used to facilitate a predilation, has been omitted for simplicity. A guidewire **430** is inserted into a branch vessel via a main vessel **402**. The guidewire **430** acts as a rail over which a delivery catheter **432** may be advanced through a patient's vasculature. The distal end of the delivery catheter **432** can include an atraumatic tip **434** to minimize or to reduce damaging the inside wall of the vasculature as the delivery catheter **432** is advanced over the guidewire **430**. A retractable sheath **436** covers a bifurcation stent **300** that is mounted to the delivery catheter **432**. When the bifurcation stent **300** is self-expandable, retraction of the retractable sheath **436** allows the bifurcation stent **300** to expand from its compressed configuration (as shown in FIG. **26**) to its expanded configuration (as shown in FIG. **23**A). The distal and proximal markers **326**, **330** allow visualization of the bifurcation stent **300** and determination of its exact location within the vasculature.

To deliver the bifurcation stent **300** to the bifurcation **400** the delivery catheter **432** is advanced along the guidewire **430** until the distal markers **326** of the bifurcation stent **300** are adjacent the carina **414**, as illustrated in FIG. **27**. Any of a variety of techniques well known to those of skill in the art may be used to visualize the markers **326** within the patient's vasculature.

Once the distal marker **326** of the bifurcation stent **300** is approximately aligned with the carinal plane **418** or just on the distal side of the carinal plane **418**, the retractable sheath **436** is partially retracted as illustrated in FIG. **28**. The retractable sheath **436** is retracted enough to expose the distal-most segment **306** of the bifurcation stent **300**. When the bifurcation stent **300** is self-expandable, the distal-most segment **306** will partially self-expand as shown in FIG. **28**. At the distal-most segment **306** expands, its distal markers **326** move apart from one another. The distal markers **326** are positioned approximately within the carinal plane **418** so that the distal peaks **320** of the bifurcation stent's distal-most segment **306** are at a location proximal of and adjacent the carina **414**.

The retractable sheath **436** is then further retracted in a proximal direction to expose the second segment **306** adjacent the distal-most segment **306** of the bifurcation stent **300**. The catheter **432** is also moved in a slight distal direction to advance the distal peaks **320** and distal markers **326** passed the carinal plane **418** so that at least the markers and optionally the distal peaks **320** are distal to the carinal plane **418**, as illustrated in FIG. **29**. At this point two adjacent struts **308** of the distal-most segment **306** which form a distally open "v" or other concavity begin to straddle the carina **414**. When straddling the carina **414** a first strut **308** can reside at least partially within the first branch vessel **404**, and a second strut **308** (which can be adjacent to the first strut **308**) can reside at least partially within the second branch vessel **406**. In other embodiments, when straddling the carina **414** a first strut **308** is directed towards the first branch vessel **404** and a second strut **308** is directed towards the second branch vessel **406**. The first strut **308** can be adjacent the second strut **308**. The exact position and orientation of the bifurcation stent **300** can be confirmed using any of a variety of visualization techniques as are known to those of skill in the art.

The bifurcation stent **300** is advanced distally until the carina **414** contacts the inside walls of the distally facing concavity leading to proximal peak **322**, which is formed between adjacent first and second struts **308** (see FIG. **27**) that are positioned within the first and second branch vessels **404**, **406**, respectively, as illustrated schematically in FIG. **30**. The retractable sheath **436** may then be fully retracted to completely release the bifurcation stent **300** from the catheter **432**. When released from the catheter **432**, the bifurcation stent **300** will expand to its fully expanded configuration and will generally conform to the inside surface of the vascular bifurcation **400**. When fully expanded, the distal peaks **320** of the distal-most segment **306** of the bifurcation stent **300** are positioned at least about 1 mm, and in some implementations from about 2 mm to about 4 mm distal of the carinal plane **418**.

Once deployed, the bifurcation stent **300** can be post dilated to assure proper stent placement and orientation. For example, a balloon catheter can be advanced to the bifurcation **400** and inflated at least partially within the bifurcation stent **300**. The balloon can be shaped such that when inflated it provides additional expansion to the distal segment **306** of the bifurcation stent **300**. In addition, a balloon catheter can be used to expand a balloon expandable bifurcation stent **300** from its compressed state to its expanded stated when delivered to the bifurcation, to achieve the deployed tapered configuration described herein.

A branch stent **500** may optionally be delivered to either or both of the branch vessels **404**, **406**, as illustrated in FIG. **31**. The branch stent **500** generally has a cylindrical shape when fully expanded in an unconstrained configuration. The branch stent **500** can include any of a variety of wall patterns or designs well known to those of skill in the art and may include cells having struts and peaks such as used with the bifurcation stent described in FIGS. **23**A and **24**A.

The branch stent **500** can be delivered over the guidewire **430** with the same catheter **432** used to deliver the bifurcation stent **300**. Alternatively, the catheter **432** used to deliver the bifurcation stent **300** may be removed from the vasculature and a second catheter containing the branch stent **500** may thereafter be provided. Any of the catheters described herein may be used to deliver the bifurcation stent **300** and/or the branch stent **500**.

In one embodiment, as illustrated in FIG. **31**, a cylindrical branch stent **500** is delivered to a branch vessel of the bifurcation **400** through the lumen **334** of the previously deployed bifurcation stent **300**. The branch stent **500** is deployed such that the proximal end **504** of the branch stent **500** partially overlaps the distal end **304** of the bifurcation stent **300**. Proximal peaks **502** of the branch stent **500** can be positioned proximal of the carinal plane **418**, thereby at least partially overlapping the distal-most cell **306** of the bifurcation stent **300**.

The stents, stent deployment systems, and methods described herein may be adapted as mentioned above to treat any of a number of bifurcations within a human patient. For example, bifurcations of both the left and right coronary arteries, the bifurcation of the carotid, femoral, iliac, popliteal, renal or other coronary bifurcations. Alternatively this apparatus may be used for nonvascular bifurcations, such as tracheal or biliary bifurcations, for example between the common bile and cystic ducts, or in the area of the bifurcation of the principal bile tract.

Although certain preferred embodiments and examples have been described herein, it will be understood by those skilled in the art that the present inventive subject matter extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the present inventive subject matter herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

What is claimed is:

1. A stent for treating a vascular bifurcation, comprising:

a first proximal end, a second distal end and a longitudinal axis therebetween;

a plurality of segments extending coaxially end to end along the longitudinal axis, each segment consisting of a single ring which forms a circumference of the stent, wherein each single ring comprises a plurality of struts extending in an end to end manner creating a zig zag pattern in which each strut extends from a proximal end of said each single ring to a distal end of said each single ring,

wherein the stent is expandable from a reduced diameter to an expanded diameter and configured to provide support to the vascular bifurcation when expanded, the second distal end having a larger diameter than the first proximal end when expanded;

wherein the plurality of segments consists of four segments and adjacent segments of said four segments are connected to each other by only straight links; and

wherein one of the single rings is positioned adjacent the second distal end and comprises three and no more than three eyelets integrally formed on a distal end of said single ring, and one of the single rings is positioned adjacent the first proximal end and comprises one and no more than one eyelet integrally formed on a proximal end of said single ring, wherein each eyelet comprises an opening configured to receive a radiopaque marker therein, and the opening is oval in shape and has a circumferential dimension greater than an axial dimension.

2. The stent of claim **1**, further comprising a radiopaque marker.

3. The stent of claim **2**, wherein the radiopaque marker is mushroom-shaped.

4. The stent of claim **2**, wherein the radiopaque marker is press-fit into one of said eyelets.

5. The stent of claim **2**, wherein the radiopaque marker comprises gold.

6. The stent of claim **2**, wherein the radiopaque marker comprises tantalum.

7. The stent of claim **2**, wherein the radiopaque marker is selected to have an electromotive force to match an electromotive force of a remainder of the stent.

8. The stent of claim **1**, wherein the eyelets integrally formed on the distal end of said single ring positioned adjacent the second distal end extend beyond a first plane extending transversally to the longitudinal axis of the stent, the stent having a plurality of apexes on said single ring positioned adjacent the second distal end, the plurality of apexes substantially positioned on the first plane, and the eyelet integrally formed on the proximal end of said single ring positioned adjacent the first proximal end extends beyond a second plane extending transversally to the longitudinal axis of the stent, the stent having a plurality of apexes on said single ring positioned adjacent the first proximal end, the plurality of apexes substantially positioned on the second plane.

9. The stent of claim **1**, wherein the stent is coated with a drug capable of being eluted over time.

10. The stent of claim **1**, wherein the stent has a tapered shape when expanded to the expanded diameter.

11. The stent of claim **10**, wherein the stent tapers along its entire length from the first proximal end to the second distal end.

12. The stent of claim **1**, wherein the stent is substantially conical in shape.

13. The stent of claim **1**, wherein the single ring positioned adjacent the first proximal end is substantially cylindrical and the single ring positioned adjacent the second distal end is substantially conical.

14. The stent of claim **1**, wherein the stent is configured to conform to a shape of the vascular bifurcation in an area of a widened transition zone when expanded.

15. A stent for treating a vascular bifurcation, comprising:

a first proximal end, a second distal end and a longitudinal axis therebetween;

a plurality of segments extending coaxially end to end along the longitudinal axis, each segment consisting of a single ring which forms a circumference of the stent, wherein each single ring comprises a plurality of struts extending in an end to end manner creating a zig zag pattern in which each strut extends from a proximal end of the said each single ring to a distal end of said each single ring,

wherein the stent is expandable from a reduced diameter to an expanded diameter and configured to provide support to the vascular bifurcation when expanded, the second distal end having a larger diameter than the first proximal end when expanded;

wherein the plurality of segments consists of five segments and adjacent segments of said five segments are connected to each other by only straight links; and

wherein one of the single rings is positioned adjacent the second distal end and comprises three and no more than three eyelets integrally formed on a distal end of said single ring, and one of the single rings is positioned adjacent the first proximal end and comprises one and no more than one eyelet integrally formed on a proximal end of said single ring, wherein each eyelet comprises an opening configured to receive a radiopaque marker therein, and the opening is oval in shape and has a circumferential dimension greater than an axial dimension.

16. The stent of claim **15**, wherein the stent has a tapered shape when expanded to the expanded diameter.

17. The stent of claim **15**, wherein the stent tapers along its entire length from the first proximal end to the second distal end.

18. The stent of claim **15**, wherein the stent is substantially conical in shape.

19. The stent of claim **15**, wherein the single ring positioned adjacent the first proximal end is substantially cylindrical and the single ring positioned adjacent the second distal end is substantially conical.

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